AUTHENTICATED
U.S. GOVERNMENT
INFORMATION
GPO

Part II begins on page 7625

Pages 7583–7657

PART I

FEDERAL REGISTER

VOLUME 29 NUMBER 116

Washington, Saturday, June 13, 1964

Contents

AGRICULTURAL MARKETING SERVICE

Rules and Regulations

Handling limitations:
  Lemons grown in California and Arizona 7590
  Oranges, Valencia, grown in Arizona and California 7589
Nectarines grown in California; expenses and assessment rate, 1964–65, and carryover of unexpended funds 7590
Tomatoes:
  Import regulations 7591
  Lower Rio Grande Valley in Texas; shipment limitation 7590
Poultry and products thereof; inspection; miscellaneous amendments 7585

AGRICULTURAL STABILIZATION AND CONSERVATION SERVICE

Rules and Regulations

Tobacco allotment and marketing quota, 1963–64 and subsequent years; miscellaneous amendments 7588

Notices

Sugarcane wages and prices in Louisiana; hearing 7612

AGRICULTURE DEPARTMENT

See also Agricultural Marketing Service; Agricultural Stabilization and Conservation Service; Commodity Credit Corporation.

Notices

California; extension of period for emergency loans 7612

ATOMIC ENERGY COMMISSION

Notices

State of North Carolina; proposed agreement for assumption of certain AEC regulatory authority 7607

CIVIL AERONAUTICS BOARD

Notices

Cordova Airline, Inc.; amendment of previous exemption orders 7613

COMMERCE DEPARTMENT

See also Maritime Administration.

Notices

Business and Defense Services Administration; organization 7612

COMMODITY CREDIT CORPORATION

Rules and Regulations

Loans, purchases, and other operations:
  Cottonseed, 1964 crop 7594
  Grain sorghum, 1964 7591

COMPTROLLER OF THE CURRENCY

Rules and Regulations

Investment securities; School Refunding Bonds, Broward County, Fla 7594

CUSTOMS BUREAU

Notices

Apple juice from Canada; purchase price and foreign market value 7611

EDUCATION OFFICE

Rules and Regulations

Loans to private nonprofit schools for acquisition of equipment for strengthening instruction in science, mathematics, and modern foreign languages 7598
Training program under Manpower and Development Training Act of 1962 7600

FEDERAL AVIATION AGENCY

Rules and Regulations

Airworthiness directives:
  Dornier Model DO–28 aircraft 7596
  Lockheed Models 49 through 1049H Series aircraft 7596
Certification, pilots and flight instructors; student pilot solo requirements in gyroplanes 7594
Federal airway segments:
  Alteration 7595
  Designation 7595
Jet route; alteration 7596
Restricted area, designation; and alteration of Federal airways 7595
Transition area; alteration 7595

Proposed Rule Making

Airworthiness directives:
  Boeing Models 707 and 720 Series aircraft 7606
  de Havilland Model 114 Heron aircraft 7605
Federal airway segment; revocation 7604
Jet routes; alteration 7604
Radio failure procedures in IFR operations 7605

Notices

Southwest Republic Corp.; determination of no hazard to air navigation 7614
WKY Television System, Inc.; determination of hazard to air navigation 7615

FEDERAL COMMUNICATIONS COMMISSION

Notices

Hearings, etc.:
  All-Florida Communications Co. et al 7615
  Bigbee Broadcasting Co 7615
  Cascade Broadcasting Co. and Sunset Broadcasting Co. (KNDX–FM) 7616
  Chronicle Publishing Co. (KRON–TV) and American Broadcasting-Paramount Theatres, Inc. (KGO–TV) 7616
  Dirigo Broadcasting, Inc., and Downeast Television, Inc 7616
  Hi-Desert Microwave, Inc 7616
  Progress Broadcasting Corp. (WHOM) 7616
  Southern Radio and Television Co. and Robert Hecksher (WMYR) 7616
  Springfield Telecasting Co. and Midwest Television, Inc 7617
  WENY, Inc., and Elmira Heights-Horseheads Broadcasting Co 7617
  Whitney Telephone Answering Service 7617

(Continued on next page)

FEDERAL POWER COMMISSION

Notices

Hearings, etc.:
- Alabama-Tennessee Natural Gas Co. 7618
- Bakke, W. E., et al. 7619
- Consumers Power Co. 7618
- Iowa Southern Utilities 7620
- Lone Star Gas Co. 7618
- Mississippi River Transmission Corp. and Mississippi River Fuel Corp. 7618
- Natural Gas Pipeline Company of America 7619
- Northern States Power Co. 7620
- Panamint Springs Resort 7619
- Southern California Edison Co. and Desert Electric Cooperative, Inc. 7621
- Transwestern Pipeline Co. et al. 7619

FOOD AND DRUG ADMINISTRATION

Rules and Regulations

Drugs, antibiotics; tests and methods of assay and certification (2 documents) 7625, 7642

Food additives:
- Ethylene-methyl acrylate copolymer resins 7597
- Further extensions of effective dates 7597
- Permitted in animal feed or supplements thereof 7597

Pesticide chemicals in or on raw agricultural commodities; status of benzaldehyde used as bee repellant 7597

Notices

Filing of petitions:
- Economics Laboratory, Inc. 7613
- Syracuse University Research Corporation 7612

HEALTH, EDUCATION, AND WELFARE DEPARTMENT

See Education Office; Food and Drug Administration.

INTERIOR DEPARTMENT

Notices

Authority delegations:
- Commissioner of Indian Affairs 7611
- Commissioner of Reclamation 7611

Fehr, Franklin Stuart; appointment and statement of business interests 7611

INTERSTATE COMMERCE COMMISSION

Notices

Fourth section applications for relief 7622

LABOR DEPARTMENT

See also Wage and Hour Division.

Notices

South Dakota Employment Security Department; opportunity for hearing 7621

MARITIME ADMINISTRATION

Notices

Farrell Lines, Inc.; application 7612

TREASURY DEPARTMENT

See Comptroller of the Currency; Customs Bureau.

WAGE AND HOUR DIVISION

Rules and Regulations

Tobacco industry in Puerto Rico; wage order 7598

Codification Guide

The following numerical guide is a list of the parts of each title of the Code of Federal Regulations affected by documents published in today's issue. A cumulative list of parts affected, covering the current month to date, appears at the end of each issue beginning with the second issue of the month.

A cumulative guide is published separately at the end of each month. The guide lists the parts and sections affected by documents published since January 1, 1964, and specifies how they are affected.

7 CFR

81	7585
724	7588
908	7589
910	7590
916	7590
965	7590
980	7591
1421	7591
1443	7594

12 CFR

1	7594

14 CFR

61 [New]	7594
71 [New] (4 documents)	7595
73 [New]	7595
75 [New]	7596
507 (2 documents)	7596
PROPOSED RULES:	
71 [New]	7604
75 [New]	7604
91 [New]	7605
507 (2 documents)	7605, 7606

21 CFR

120	7597
121 (3 documents)	7597
146 (2 documents)	7625, 7642
148	7626
148a	7627
148b	7629
148c	7631
148d	7634
148e	7643
148f	7636
148h	7637
148j	7653
148m	7640
148o	7655

29 CFR

657	7598

45 CFR

142	7598
160	7600

Volume 77

UNITED STATES STATUTES AT LARGE

[88th Cong., 1st Sess.]

Contains laws and concurrent resolutions enacted by the Congress during 1963, reorganization plan, and Presidential proclamations. Included is a numerical listing of bills enacted into public and private law, and a guide to the legislative history of bills enacted into public law.

Price: $7.50

Published by Office of the Federal Register, National Archives and Records Service, General Services Administration

Order from Superintendent of Documents, Government Printing Office, Washington, D.C. 20402

Rules and Regulations

Title 7—AGRICULTURE

Chapter I—Agricultural Marketing Service (Standards, Inspections, Marketing Practices), Department of Agriculture

SUBCHAPTER D—REGULATIONS UNDER THE POULTRY PRODUCTS INSPECTION ACT

PART 81—INSPECTION OF POULTRY AND POULTRY PRODUCTS

Miscellaneous Amendments

Under authority contained in the Poultry Products Inspection Act (21 U.S.C. 451 et seq.), the United States Department of Agriculture hereby amends the Regulations Governing the Inspection of Poultry and Poultry Products (7 CFR Part 81) as set forth below.

Statement of considerations. The amendments increase the hourly rate for overtime and holiday inspection service from $5.00 per hour to $5.80 per hour and change the hourly rate of appeal inspections which are found to be frivolous from $5.40 per hour to $5.80 per hour. The cost of overtime and holiday inspection service is required by the Poultry Products Inspection Act to be paid for by applicants for inspection under the Act. This change is necessary due to the general salary increases of Federal employees in October 1962 and January 1964, the reclassification of certain inspector positions, and determination that night differential is payable to employees who perform overtime work between the hours of 6:00 p.m. and 6:00 a.m.

Prior to June 1, 1960, the rate for overtime and holiday work was $5.40 per hour. This rate was established on a computed basis and, as experience was gained under the Act, was found to be too high. Accodingly, it was reduced, effective June 1, 1960, to the current rate of $5.00 per hour. As a result of the prior high scale, a balance was accumulated in the fund. Due to salary increases and reclassifications of positions, the cost has, for some time, exceeded this $5.00 charge. The balance in the overtime and holiday fund has been used to subsidize this insufficient charge. This fund has now been reduced by a substantial amount, thus returning to the plants that portion of the earlier charge which was in excess of costs. Because of the reasons previously mentioned and because the fund has now been reduced to the minimum level advisable in accordance with good fiscal procedure, it is necessary to increase the rate.

On April 4, 1964, there was published in the FEDERAL REGISTER a notice of proposed amendments which would make slight changes in the sections concerning application for inspection service, facilities required at processing plants and ice and water chilling. The proposal also provided for minimum cooking temperatures for all heat processed poultry rolls in order to provide protection against non-spore forming pathogenic bacteria, for the exception from the requirements of foreign inspection certificates and port of arrival inspection of small quantities of imported poultry and poultry products entering this country exclusively for the personal use of the consignee or for display or laboratory analysis by the consignee, and for the average basis weight, moisture absorption and size of giblet wrapping paper. Accordingly, the present amendments make the slight changes in the sections on application for inspection service, facilities required at processing plants and importations of small quantities of poultry products exclusively for the personal use of the consignee. Minimum cooking temperatures are established for heat processed poultry rolls and the average basis weight, moisture absorption and size of giblet wrapping material is specified.

No change is being made in the section on ice and water chilling. The proposed change to this section was for the purpose of clarifying our present requirements. During the time for receiving comments, the Department has found that the requirements are fully understood and need no further clarification. No substantive changes have been made in the proposed amendments of April 4 but the wording has been changed in some sections for the sake of clarity.

In addition, there are a number of sections and paragraphs included in the amendments solely for the purpose of effecting editorial changes which improve the format of the regulations. There are no other changes in these sections. Such sections and paragraphs are: §§ 81.14(g); 81.50(g); 81.71; 81.95(c); 81.120; 81.121; 81.129; 81.130(a)(6); 81.156; 81.173; 81.204; 81.300; 81.301; and 81.309. Sections 81.2; 81.52(f); 81.146; and 81.155 are deleted since they are no longer applicable and serve no useful purpose.

The amendments are as follows:

§ 81.2 [Deleted]

1. Delete § 81.2 and the heading "Poultry Products Inspection Act" preceding said section.

2. Section 81.14 (a) (1), (2), and (5), (b)(2), (c)(13) and (e)(2) are hereby amended to read:

§ 81.14 Approval of application for inspection.

* * * * *

(a) *Prints of drawings and specifications to be furnished.* (1) Applicants for inspection service may obtain information or assistance from the Inspection Service with respect to the requirements before submitting prints of drawings and specifications.

(2) Four prints of drawings showing the features specified in this section shall be submitted to the Administrator. Photostats of drawings are not acceptable. The drawings and prints shall be legible, made with sharp, clear lines, and properly drawn to scale and shall consist of complete floor plans and a plot plan. Elevations of all sides of all buildings shall be shown on the drawings, or four copies of photographs showing all sides of all buildings shall accompany the original submission. Submissions consisting of more than one sheet shall be bound together at the left margin in sets.

* * * * *

(5) The sheets of paper on which prints of drawings are made shall not exceed a size of 34" x 44". The drawings, other than of the plot plan, shall be made to a scale of ⅛" per foot. The plot plan may be drawn to a scale of not less than 1/32" per foot. The drawings shall indicate the scale used and shall also indicate the floor shown (e.g. basement, first, or second).

(b) *Features required to be shown on floor plan.* * * *

(2) The name of the firm and address of the plant by street and street number, or by other means properly identifying the location of the plant, shall be shown on each drawing the same as shown on the application for service (Form PY 500).

* * * * *

(c) *Specifications.* * * *

(13) Approximate rate of production—for slaughtering and/or eviscerating establishments, indicate hourly rate of slaughter and/or evisceration for each class of poultry, and for other types of establishments, indicate pounds of each class or type of poultry products processed per hour.

* * * * *

(e) *Changes in drawings.* * * *

(2) Pasters of minor changes which may be affixed to the affected areas on the previously approved drawings in a manner not obscuring essential data. Paster drawings shall be prepared to the same scale and presented on a background similar to that of the originally approved drawing.

* * * * *

3. Section 81.14(g) is hereby republished to read:

§ 81.14 Approval of application for inspection.

* * * * *

(g) *Survey and plant approval.* Prior to the inauguration of the inspection service, a survey of the plant and premises shall be made by a representative of the Inspection Service to determine if the plant is constructed and facilities are installed in accordance with the approved drawings, specifications and the regulations in this part. The application for inspection service may be granted and the plant may be approved by the Administrator only when these requirements have been met. The Administrator may terminate plant approval of any official establishment in which inspection service has been discontinued.

* * * * *

4. Section 81.33(a) is hereby amended to read:

§ 81.33 Rooms and compartments.

* * * * *

(a) *Refuse rooms.* A separate refuse room, or other equally adequate facilities, shall be required in official establishments where accumulations of refuse occur. Refuse rooms shall be entirely separate from other rooms in the establishment, have tight fitting doors, be properly ventilated, and have adequate drainage and cleanup facilities, and the floors and walls to a height of six feet above the floor shall be impervious to moisture, and walls above that height, and ceilings, shall be moisture resistant.

* * * * *

5. Section 81.35(b) (1), (2), and (3) are hereby amended to read:

§ 81.35 Draining and plumbing.

* * * * *

(b) *Sewage and plant wastes.* (1) The sewer system shall have adequate slope and capacity to remove readily all waste from the various processing operations and to minimize or, if possible, prevent stoppage and surcharging of the system.

(2) Interceptor traps which are connected with the sewer system shall be suitably located, and not near any edible products department or in any area where products are unloaded from or loaded into vehicles. To facilitate cleaning, such traps shall have inclined bottoms and be provided with suitable covers.

(3) Each floor drain shall be equipped with a deep seal trap and the plumbing shall be installed so as to prevent sewage from backing up and flooding the floor, except that floor drains in areas not regularly washed down will be acceptable without deep seal traps: *Provided,* That such drains are connected to secondary drainage systems discharging into a safe sink or basin (air gap) that is properly trapped and vented: *And provided further,* That such drains accomplish the objectives and intent of this paragraph.

* * * * *

6. Section 81.50(d) is hereby amended to read:

§ 81.50 Temperatures and cooling and freezing procedures.

(d) *Cooling giblets.* Giblets shall be chilled to 40° F. or lower within 2 hours from the time they are removed from the inedible viscera, except that when they are cooled with the carcass the requirements of paragraphs (b)(2) and (f)(4) of this section shall apply. Any of the acceptable methods of chilling the poultry carcass may be followed in cooling giblets, except that unwrapped livers shall not be cooled in agitated ice and water chilling media for a period in excess of 20 minutes, but may be cooled in perforated containers which are immersed in noncirculated ice and water chilling media: *Provided,* That the livers are removed from the chilling containers when their temperature has been lowered to 40° F. When ready-to-cook birds are to be consumer packaged, the giblets shall be handled in a manner that will prevent free water from being included in the giblet package. The average basis weight of giblet wrapping material shall be not more than 30 pounds per standard ream (24" x 36"—500 sheets) when tested in accordance with the Technical Association of the Pulp and Paper Industry (T.A.P.P.I.) Standard T–410. Test samples shall be conditioned in accordance with T.A.P.P.I. Standard T–402. The sample to be tested shall consist of 10 sheets representative of the shipment or lot, and individual sheets within the sample may vary within normal tolerance from the required basis weight, but the average of the sample (10 sheets) shall not weigh in excess of 30 pounds per standard ream (24" x 36"—500 sheets). The moisture absorption shall not exceed 200 percent of the dry weight (as conditioned in accordance with T.A.P.P.I. Standard T–402) and giblet wrappers (uncreped) shall not exceed the following sizes or equivalents: Chickens and Ducks, 9" x 12", Turkeys, 12" x 14".

* * * * *

7. Paragraph 81.50(g) is hereby republished to read:

(g) *Ice-pack containers.* When poultry is ice packed in barrels or other containers, the barrels and containers shall be covered and shall have an adequate number of drain holes to permit the water to drain out. However, the Administrator, upon written request and under such conditions as he may prescribe, may approve the shipment of poultry in operational type containers, such as chill tanks or lugs, from one official establishment to another official establishment for further processing.

8. Delete § 81.52(f).

9. Section 81.71 is hereby republished to read:

POST-MORTEM INSPECTION

§ 81.71 Evisceration.

No viscera or any part thereof shall be removed from any dressed poultry which is to be processed under inspection in any official establishment, except at the time of evisceration and inspection. Each carcass to be eviscerated shall be opened so as to expose the organs and the body cavity for proper examination by the inspector and shall be prepared immediately after inspection as ready-to-cook poultry. If a carcass is frozen, it shall be thoroughly thawed before being opened for examination by the inspector. Each carcass, or all parts comprising such carcass, shall be examined by the inspector. However, the Administrator may, whenever he deems it advisable and under such conditions as he may require to carry out the purposes of the act, authorize the removal, from any carcass or parts thereof, prior to inspection, of any part which will not be used in the preparation of any edible product.

10. Section 81.95(c) is hereby republished to read:

REINSPECTION AND INGREDIENTS

§ 81.95 Reinspection of poultry products; ingredients.

* * * * *

(c) All substances and ingredients used in the manufacture or preparation of any poultry product shall be clean, sound, wholesome, and fit for human food. Liquid and frozen egg products used in the preparation of any poultry product shall have been prepared under continuous inspection of the Department.

* * * * *

11. Section 81.98 is hereby amended to read:

APPEALS

§ 81.98 Appeal inspections; how made.

Any person receiving inspection service may, if dissatisfied with any decision of an inspector relating to any inspection, file an appeal from such decision: *Provided,* That such appeal is filed within 48 hours from the time the decision was made. Any such appeal from a decision of an inspector shall be made to his immediate superior having jurisdiction over the subject matter of the appeal. Review of such appeal findings, when requested, shall be made by the immediate superior of the employee of the Department making the appeal inspection. The cost of any such appeal shall be borne by the appellant if the Administrator determines that the appeal is frivolous. The charges for such frivolous appeal shall be at the rate of $5.80 per hour for the time required to make the appeal inspection.

12. The center heading preceding § 81.100 is hereby amended to read:

CANNING OR COOKING REQUIREMENTS

13. Add a new § 81.101 to read:

§ 81.101 Cooking of poultry rolls required.

When poultry rolls are heat processed in any manner, cured and smoked poultry rolls shall reach an internal temperature of at least 155° F. prior to being removed from the cooking media, and all other poultry rolls shall reach an internal temperature of at least 160° F. prior to being removed from the cooking media.

14. Sections 81.120 and 81.121 are hereby republished to read:

§ 81.120 Special procedure or requirements as to certification of slaughtered poultry for export to certain countries.

When export certificates are required by any foreign country for slaughtered poultry exported to such country, the Administrator shall prescribe or approve the form of export certificate to be used and the methods and procedures as he deems appropriate with respect to the preparation and transportation of such poultry, in order to comply with requirements specified by the foreign country regarding the exported products.

§ 81.121 Poultry inspection certificates; issuance and disposition.

(a) Upon the request of an interested party, any veterinary inspector is authorized to issue a poultry inspection certificate with respect to any lot of dressed poultry inspected by him. Each certificate shall be signed by the inspector who made the inspection covered by the certificate, and if more than one inspector participated in the inspection of the lot of poultry, each such inspector shall sign the certificate with respect to such lot. If the inspection of a lot covered by a certificate was made by a lay inspector, such certificate shall also be signed by the station supervisor or by the inspector in charge of the substation when such inspection was made. Any inspector is authorized to issue a poultry inspection certificate with respect to any poultry product inspected by him.

(b) The original and one copy of each poultry inspection certificate shall be issued to the applicant who requested such certificate, one copy shall be forwarded to the Area Supervisor, and one copy shall be retained by the inspector for filing. The inspector who issues any inspection certificate is authorized to furnish an additional copy of such certificate upon the request of an interested party.

15. Section 81.129 is hereby republished to read:

§ 81.129 Wording and form of the inspection mark.

Except as otherwise authorized, the inspection mark required to be used with respect to inspected poultry products shall include wording as follows: "Inspected for wholesomeness by U.S. Department of Agriculture." This wording shall be contained within a circle. The form and arrangement of such wording shall be exactly as indicated in the example in Figure 1, except that the appropriate plant number shall be shown, and if the plant number appears elsewhere on the labeling material in the manner prescribed in § 81.130(a)(6), it may be omitted from the inspection mark. The Administrator may approve the use of abbreviations of such inspection mark; and such approved abbreviations shall have the same force and effect as the inspection mark. The inspection mark, or the approved abbreviation thereof, shall be printed on consumer packages, or on a label to be securely affixed to such packages. The inspection mark, or approved abbreviation thereof, shall be applied to shipping containers and may be printed or stenciled thereon, but shall not be applied by rubber stamping.

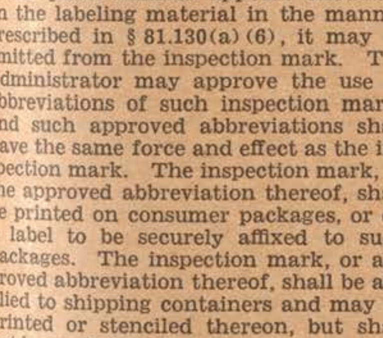

FIGURE 1.

16. Section 81.130(a)(6) is hereby republished to read:

§ 81.130 Wording and labels.

(a) * * *

(6) The plant number of the official establishment in which the product was inspected, either within the official inspection mark or clearly visible and in close proximity elsewhere on the exterior of the container, or in the case of canned product, the plant number may be embossed on the lid of each can. In the case of nontransparent consumer packages such as cartons, the plant number may be legibly printed thereon or it may be shown on an insert label placed on top of the product within the package. In the case of transparent wrappers, the plant number may be shown on an insert label and so placed under the transparent covering that it will be clearly visible and legible.

* * * * *

§ 81.146 [Deleted]

17. Delete § 81.146.

§ 81.155 [Deleted]

18. Delete § 81.155.

19. Section 81.156 is hereby republished to read:

§ 81.156 Distribution of inspected products to small lot buyers.

For the purpose of facilitating the distribution in commerce of inspected poultry products to small lot buyers (such as small restaurants), distributors or jobbers may remove inspected poultry products from shipping containers or immediate containers, other than consumer packages, and place them into other shipping containers which do not bear the inspection mark: *Provided*, That the individual carcasses or consumer packages of the poultry products bear the inspection mark and the plant number of the establishment that processed such products: *And provided further*, That the shipping container is marked with the name and address of the distributor or jobber and bears the statement "The poultry product contained herein was inspected by the U.S.D.A." However in lieu of such statement the container of imported products shall bear a statement that "The products contained herein have been approved for importation under P.P.I.A."

20. Section 81.170 is hereby amended to read:

§ 81.170 Overtime inspection service.

When operations in an official establishment require the services of inspection personnel beyond their regularly assigned tour of duty on any day, or on a day outside the established schedule, such services are considered as overtime work. The official establishment shall give reasonable advance notice to the inspector in charge for any overtime service necessary and shall pay the Secretary for such overtime at a rate of $5.80 per hour to cover the cost thereof.

21. Section 81.171(a) is hereby amended to read:

§ 81.171 Holiday inspection service.

(a) When an official establishment requires inspection service on a holiday, such service is considered holiday work. The official establishment shall, in advance of such holiday work, request the inspector in charge to furnish inspection service during such period and shall pay the Secretary therefor at the rate of $5.80 per hour. Service in excess of 8 hours for that day is considered overtime and shall be paid for at the overtime rate.

* * * * *

22. Section 81.172 is hereby amended to read:

§ 81.172 Supervisor overtime or holiday service.

When, because an establishment requires overtime service as provided in § 81.170 or requires holiday service as provided in § 81.171, a station supervisor (veterinarian) is required to work overtime or on a holiday, in the establishment, in order to supervise the service or to make final condemnation, the establishment shall pay the Secretary for such overtime or holiday work at the rate of $5.80 per hour.

23. Section 81.173 is hereby republished to read:

§ 81.173 Basis of billing establishments.

Overtime and/or holiday services shall be billed to the official establishments on the basis of each 15 minutes of overtime and/or holiday service performed by each inspector including supervisor providing such service to the establishment, except that when an official establishment requires the services of an inspector after he has completed his day's assignment and left the establishment or when he is called back to duty on a day outside of the established normal operating schedule or on a holiday, the official establishment shall pay for a minimum of two hours' service at the applicable established rate. Bills are payable upon receipt and become delinquent immediately following the end of the month in which they were rendered. Overtime or holiday inspection service will not be performed at any establishment that is delinquent and processing operations shall be confined to the regular operating schedule of the establishment.

24. The heading preceding § 81.200 is hereby amended to read:

EXEMPTIONS

25. Section 81.204 is hereby republished to read:

§ 81.204 Effect of exemptions on other persons.

Whenever a slaughterer or processor is granted an exemption under § 81.203 with respect to the slaughtering or processing of any poultry or poultry products under this subpart, under specified conditions, the sale, offer for sale, transportation and other handling in commerce by any person of such poultry and poultry products in accordance with such conditions is hereby authorized, except as restricted by the act.

26. The heading preceding § 81.300 is hereby amended to read:

IMPORTS

27. Section 81.300 is hereby republished to read:

§ 81.300 Requirements for importation into United States; definition of United States.

Slaughtered poultry or poultry products may be imported into the United States from any foreign country only in accordance with the regulations in this subpart. Dressed poultry may be imported into the United States only if it is consigned to an official establishment for inspection under the act. The term "United States," as used in this subpart, means the States, the District of Columbia and Puerto Rico.

28. Section 81.301(a) is hereby republished to read:

§ 81.301 Eligibility of foreign countries for importation of products into the United States.

(a) Whenever it is determined by the Administrator that the system of poultry inspection maintained by any foreign country is the substantial equivalent of the system maintained by the United States, notice of that fact will be given by listing the name of such foreign country in paragraph (b) of this section. Thereafter slaughtered poultry and poultry products from the countries so listed shall be eligible, subject to the provisions of this subpart and other applicable laws and regulations, for importation into the United States. Such products to be imported into the United States from these foreign countries must meet, to the extent applicable, the same standards and requirements that apply to comparable domestic products as set forth in the regulations in this entire part. Slaughtered poultry and poultry products from foreign countries not listed herein are not eligible for importation into the United States, except as provided by § 81.311. In determining whether the inspection system of a foreign country is the substantial equivalent of the system maintained by the United States, the Administrator shall review the inspection regulations of the foreign country and make a survey to determine the manner in which the inspection system is administered within the foreign country. The survey of the foreign inspection system may be expedited by payment by the interested Government agency in the foreign country of the travel expenses incurred in making the survey.

* * * * *

29. Section 81.309 is hereby republished to read:

§ 81.309 Labeling of consumer packages of product for importation.

(a) Consumer packages of product offered for importation shall bear a label, printed in English, showing (1) the name of product; (2) the name of the country of origin preceded by the words "Product of," which statement shall appear immediately under the name of the product; (3) the word "Ingredients" followed by a list of the ingredients in case of product fabricated from two or more ingredients, including a declaration of artificial flavors, colors, or preservatives, if any; (4) the name and place of business of manufacturer, packer or distributor, qualified by a phrase which reveals the connection that such person has with the product; (5) an accurate statement of the quantity of contents; (6) the inspection mark of the country of origin; and (7) the plant number of the establishment at which the product was prepared.

(b) The labels shall not be false or misleading in any respect.

30. Section 81.311 is hereby amended to read:

§ 81.311 Small importations for consignee's personal use, display, or laboratory analysis.

Any product (other than dressed poultry which is forbidden entry by other Federal law or regulation) which is offered for importation in quantities of less than 10 pounds net weight, exclusively for the personal use of the consignee, or for display or laboratory analysis by the consignee, and not for sale or distribution; which is sound, healthful, wholesome, and fit for human food; and which is not adulterated and contains no substance not permitted by the Act or regulations in this part, may be admitted into the United States without a foreign inspection certificate, and such product is not required to be inspected upon arrival in the United States and may be shipped to the consignee without further restriction under this part: *Provided*, That the Department may, with respect to any specific importation, require that the consignee certify that such product is exclusively for the personal use of said consignee, or for display or laboratory analysis by said consignee, and not for sale or distribution.

31. The heading for Subpart B preceding § 81.400 is hereby amended to read:

Subpart B—Interpretations and Statements of Policy

(Sec. 14, 71 Stat. 447; 21 U.S.C. 463; 19 F.R. 74, as amended)

Except for the increase in the hourly rates for overtime and holiday inspection service and the hourly rate for appeal inspections which are found to be frivolous, notice has been published with respect to the amendments of the regulations which are substantive in nature and affect the rights of individuals. Regarding the changes in the rates, the Poultry Products Inspection Act requires that the cost of overtime and holiday inspection service be borne by the applicant. The facts upon which the determinations with respect to charges necessary to cover overtime and holiday inspection costs are made are not available to the industry, but are peculiarly within the knowledge of the Department. Therefore, public rule making would not result in the Department receiving data and facts on this matter. The other changes in the regulations which were not included in such notice of rule making are nonsubstantive in nature and do not affect the rights of any person. Affected persons do not need time in which to conform their operations to the new requirements and the changes in rates should become effective July 1, 1964, for the sake of uniformity of accounting. Accordingly, under section 4 of the Administrative Procedure Act (5 U.S.C. 1003), it is found upon good cause that notice and public procedure with respect to the nonsubstantive changes and the changes in hourly rates included in the amendments are impracticable and unnecessary, and good cause is found for making all the amendments effective less than 30 days after publication in the FEDERAL REGISTER.

Issued at Washington, D.C., this 8th day of June, 1964, to become effective on July 1, 1964.

G. R. GRANGE,
Deputy Administrator Marketing Services.

[F.R. Doc. 64-5819; Filed, June 12, 1964; 8:45 a.m.]

Chapter VII—Agricultural Stabilization and Conservation Service (Agricultural Adjustment), Department of Agriculture

SUBCHAPTER B—FARM MARKETING QUOTAS AND ACREAGE ALLOTMENTS

[Amdt. 8]

PART 724—BURLEY, FLUE-CURED, FIRE-CURED, DARK AIR-CURED, VIRGINIA SUN-CURED, CIGAR-BINDER (TYPES 51 AND 52), CIGAR-FILLER AND BINDER (TYPES 42, 43, 44, 53, 54, AND 55) AND MARYLAND TOBACCO

Subpart—Tobacco Allotment and Marketing Quota Regulations, 1963–64 and Subsequent Marketing Years

MISCELLANEOUS AMENDMENTS

1. *Basis and purpose.* The amendment contained herein is issued pursuant to the Agricultural Adjustment Act of 1938, as amended (7 U.S.C. 1281 et seq.), and is made for the purpose of amending the Tobacco Allotment and Marketing Quota Regulations for the 1963–64 and Subsequent Marketing Years (27 F.R. 8937, 9211, 10743; 28 F.R. 7757, 8018, 9144, 11049; 29 F.R. 1315, 6520).

The amendment (1) clarifies the definition of a new farm, (2) provides that the marketing recorder shall enter the seller's name(s) on the "county copy" of the sale memo only when the name(s) of the person(s) shown on the floor sheet as seller does not include the last name of the person to whom the marketing card was issued, and (3) establishes the basic penalty rates for the 1964–65 marketing year for all kinds of tobacco except Maryland tobacco. As sales of the 1963 crop of Maryland tobacco are now underway and sales of the 1964 Flue-cured tobacco crop will soon begin, it is necessary that the part of this amendment which relates to the sale memo be made effective at the earliest possible date. Furthermore, the change in the definition of a new farm is for clarification only and the basic penalty rate for all kinds of tobacco is the result of a mathematical calculation provided for by the Act. Accordingly, it is hereby found and determined that compliance with the notice, public procedure, and effective date requirements of section 4 of the Administrative Procedure Act (5 U.S.C. 1003) is impracticable and contrary to the public interest, and the amendment contained herein shall be effective upon publication in the FEDERAL REGISTER.

2. The Tobacco Allotment and Marketing Quota Regulations for the 1963–64

and Subsequent Marketing Years (27 F.R. 8937, 9211, 10743; 28 F.R. 7757, 8018, 9144, 11049; 29 F.R. 1315, 6520) are hereby amended as follows:

a. Paragraph (p), as amended, of § 724.51 is amended to read as follows:

§ 724.51 Definitions.

* * * * *

(p) "New farm" means a farm for which a tobacco allotment is established in the current year and for which there is no tobacco history acreage in the base period. If, in accordance with applicable law and regulations, no tobacco acreage allotment was determined for the farm for any year of the base period, any production of tobacco on such farm during the base period shall not be considered in determining whether the farm is a new farm. The term "tobacco history acreage" as used in this paragraph shall be as defined and explained in § 724.55.

* * * * *

b. Paragraph (f) of § 724.90 is amended to read as follows:

§ 724.90 Identification of marketings, excluding cigar tobacco.

* * * * *

(f) *Recording names of additional producers.* The marketing recorder shall enter the seller's name(s) on the "county copy" of the sale memo when the name(s) of the person(s) shown on the floor sheet as seller does not include the last name of the person to whom the marketing card was issued.

* * * * *

c. Section 724.92, as amended, is amended to read as follows:

§ 724.92 Rate of penalty.

(a) *Basic rate.* The basic penalty rate shall be equal to seventy-five (75) percent of the average market price for the kind of tobacco for the immediately preceding marketing year as determined by the Crop Reporting Board, Statistical Reporting Service, United States Department of Agriculture. The rate of penalty will be determined for each marketing year and announced by amendment to the regulations of this subpart.

(b) *1962-63 average market price.* The average market price as determined by the Crop Reporting Board for the 1962-63 marketing year was:

AVERAGE MARKET PRICE

Kind of tobacco:	*Cents per pound*
Burley	98.5
Flue-cured	60.1
Fire-cured (type 21)	38.8
Fire-cured (types 22, 23, and 24)	38.7
Dark air-cured	36.2
Virginia sun-cured	37.4
Cigar-filler and binder (types 42, 43, 44, 53, 54, and 55)	29.0
Cigar-binder (types 51 and 52)	48.5
Maryland	55.2

(c) *1963-64 rate of penalty per pound.* The penalty per pound upon marketings of excess tobacco subject to marketing quotas during the 1963-64 marketing year shall be:

RATE OF PENALTY

Kind of tobacco:	*Cents per pound*
Burley	44
Flue-cured	45
Fire-cured (type 21)	29
Fire-cured (types 22, 23, and 24)	29
Dark air-cured	27
Virginia sun-cured	28
Cigar-filler and binder (types 42, 43, 44, 53, 54, and 55)	22
Cigar-binder (types 51 and 52)	36
Maryland	41

(d) *1963-64 average market price.* The average market price as determined by the Crop Reporting Board for the 1963-64 marketing year was:

AVERAGE MARKET PRICE

Kind of tobacco:	*Cents per pound*
Burley	59.1
Flue-cured	58.0
Fire-cured (type 21)	35.5
Fire-cured (types 22, 23, and 24)	36.9
Dark air-cured	33.3
Virginia sun-cured	31.4
Cigar-filler and binder (types 42, 43, 44, 53, 54, and 55)	29.8
Cigar-binder (types 51 and 52)	45.9
Maryland	(1)

[1] Will be issued by amendment to the regulations of this subpart.

(e) *1964-65 rate of penalty per pound.* The penalty rate per pound upon marketings of excess tobacco subject to marketing quotas during the 1963-64 marketing shall be:

RATE OF PENALTY

Kind of tobacco:	*Cents per pound*
Burley	44
Flue-cured	43
Fire-cured (type 21)	27
Fire-cured (types 22, 23, and 24)	28
Dark air-cured	25
Virginia sun-cured	24
Cigar-filler and binder (types 42, 43, 44, 53, 54, and 55)	22
Cigar-binder (types 51 and 52)	34
Maryland	(1)

[1] Will be issued by amendment to the regulations of this subpart.

(Secs. 314, 375, 52 Stat. 48, as amended, 66, as amended; 7 U.S.C. 1314, 1375)

Effective date. Date of publication in the FEDERAL REGISTER.

Signed at Washington, D.C., on June 10, 1964.

E. A. JAENKE,
Acting Administrator, Agricultural Stabilization and Conservation Service.

[F.R. Doc. 64-5899; Filed, June 12, 1964; 8:49 a.m.]

Chapter IX—Agricultural Marketing Service (Marketing Agreements and Orders; Fruits, Vegetables, Tree Nuts), Department of Agriculture

[Valencia Orange Reg. 88]

PART 908—VALENCIA ORANGES GROWN IN ARIZONA AND DESIGNATED PART OF CALIFORNIA

Limitation of Handling

§ 908.388 Valencia Orange Regulation 88.

(a) *Findings.* (1) Pursuant to the marketing agreement, as amended, and Order No. 908, as amended (7 CFR Part 908; 27 F.R. 10089), regulating the handling of Valencia oranges grown in Arizona and designated part of California, effective under the applicable provisions of the Agricultural Marketing Agreement Act of 1937, as amended (7 U.S.C. 601-674), and upon the basis of the recommendations and information submitted by the Valencia Orange Administrative Committee, established under the said amended marketing agreement and order, and upon other available information, it is hereby found that the limitation of handling of such Valencia oranges, as hereinafter provided, will tend to effectuate the declared policy of the act.

(2) It is hereby further found that it is impracticable and contrary to the public interest to give preliminary notice, engage in public rule making procedure, and postpone the effective date of this section until 30 days after publication hereof in the FEDERAL REGISTER (5 U.S.C. 1001-1011) because the time intervening between the date when information upon which this section is based became available and the time when this section must become effective in order to effectuate the declared policy of the act is insufficient, and a reasonable time is permitted, under the circumstances, for preparation for such effective time; and good cause exists for making the provisions hereof effective as hereinafter set forth. The committee held an open meeting during the current week, after giving due notice thereof, to consider supply and market conditions for Valencia oranges and the need for regulation; interested persons were afforded an opportunity to submit information and views at this meeting; the recommendation and supporting information for regulation during the period specified herein were promptly submitted to the Department after such meeting was held; the provisions of this section, including its effective time, are identical with the aforesaid recommendation of the committee, and information concerning such provisions and effective time has been disseminated among handlers of such Valencia oranges; it is necessary, in order to effectuate the declared policy of the act, to make this section effective during the period herein specified; and compliance with this section will not require any special preparation on the part of persons subject hereto which cannot be completed on or before the effective date hereof. Such committee meeting was held on June 11, 1964.

(b) *Order.* (1) The respective quantities of Valencia oranges grown in Arizona and designated part of California which may be handled during the period beginning at 12:01 a.m., P.s.t., June 14, 1964, and ending at 12:01 a.m., P.s.t., June 21, 1964, are hereby fixed as follows:

(i) District 1: 200,000 cartons;
(ii) District 2: 300,000 cartons;
(iii) District 3: Unlimited movement.

(2) As used in this section, "handled," "handler," "District 1," "District 2," and "District 3," and "carton" have the same

meaning as when used in said amended marketing agreement and order.

(Secs. 1–19, 48 Stat. 31, as amended; 7 U.S.C. 601–674).

Dated: June 12, 1964.

PAUL A. NICHOLSON,
Deputy Director, Fruit and Vegetable Division, Agricultural Marketing Service.

[F.R. Doc. 64–5981; Filed, June 12, 1964; 11:20 a.m.]

[Lemon Reg. 115]

PART 910—LEMONS GROWN IN CALIFORNIA AND ARIZONA

Limitation of Handling

§ 910.415 Lemon Regulation 115.

(a) *Findings.* (1) Pursuant to the marketing agreement, as amended, and Order No. 910, as amended (7 CFR Part 910; 27 F.R. 8346), regulating the handling of lemons grown in California and Arizona, effective under the applicable provisions of the Agricultural Marketing Agreement Act of 1937, as amended (7 U.S.C. 601–674), and upon the basis of the recommendation and information submitted by the Lemon Administrative Committee, established under the said amended marketing agreement and order, and upon other available information, it is hereby found that the limitation of handling of such lemons as hereinafter provided will tend to effectuate the declared policy of the act.

(2) It is hereby further found that it is impracticable and contrary to the public interest to give preliminary notice, engage in public rule making procedure, and postpone the effective date of this section until 30 days after publication hereof in the FEDERAL REGISTER (5 U.S.C. 1001–1011) because the time intervening between the date when information upon which this section is based became available and the time when this section must become effective in order to effectuate the declared policy of the act is insufficient, and a reasonable time is permitted, under the circumstances, for preparation for such effective time; and good cause exists for making the provisions hereof effective as hereinafter set forth. The committee held an open meeting during the current week, after giving due notice thereof, to consider supply and market conditions for lemons and the need for regulation; interested persons were afforded an opportunity to submit information and views at this meeting; the recommendation and supporting information for regulation during the period specified herein were promptly submitted to the Department after such meeting was held; the provisions of this section, including its effective time, are identical with the aforesaid recommendation of the committee, and information concerning such provisions and effective time has been disseminated among handlers of such lemons; it is necessary, in order to effectuate the declared policy of the act, to make this section effective during the period herein specified; and compliance with this section will not require any special preparation on the part of persons subject hereto which cannot be completed on or before the effective date hereof. Such committee meeting was held on June 9, 1964.

(b) *Order.* (1) The respective quantities of lemons grown in California and Arizona which may be handled during the period beginning at 12:01 a.m., P.s.t., June 14, 1964, and ending at 12:01 a.m., P.s.t., June 21, 1964, are hereby fixed as follows:

(i) District 1: Unlimited movement;
(ii) District 2: 441,750 cartons;
(iii) District 3: Unlimited movement.

(2) As used in this section, "handled," "District 1," "District 2," "District 3," and "carton" have the same meaning as when used in the said amended marketing agreement and order.

(Secs. 1–19, 48 Stat. 31, as amended; 7 U.S.C. 601–674)

Dated: June 11, 1964.

PAUL A. NICHOLSON,
Deputy Director, Fruit and Vegetable Division, Agricultural Marketing Service.

[F.R. Doc. 64–5928; Filed, June 12, 1964; 8:50 a.m.]

PART 916—NECTARINES GROWN IN CALIFORNIA

Determination Relative to Expenses and Fixing of Rate of Assessment for 1964–65 Fiscal Period and Carryover of Unexpended Funds

Notice was published in the May 26, 1964, issue of the FEDERAL REGISTER (29 F.R. 6873) that consideration was being given to proposals regarding the expenses and the fixing of the rate of assessment for the fiscal period ending February 28, 1965, under the marketing agreement and Order No. 916 (7 CFR Part 916) regulating the handling of nectarines grown in California, effective under the applicable provisions of the Agricultural Marketing Agreement Act of 1937, as amended (7 U.S.C. 601–674). After consideration of all relevant matters presented, including the proposals set forth in such notice which were submitted by the Nectarine Administrative Committee (established pursuant to said marketing agreement and order), it is hereby found and determined that:

§ 916.203 Expenses and rate of assessment for the 1964–65 fiscal period.

(a) *Expenses.* The expenses that are reasonable and likely to be incurred by the Nectarine Administrative Committee, established pursuant to the provisions of the aforesaid marketing agreement and order, to enable such committee to perform its functions, in accordance with the provisions thereof, during the fiscal period beginning March 1, 1964, and ending February 28, 1965, will amount to $157,670.

(b) *Rate of assessment.* The rate of assessment, which each handler who first handles nectarines shall pay as his pro rata share of the aforementioned expenses in accordance with the applicable provisions of said marketing agreement and order, is hereby fixed at two and seven-tenths cents ($0.027) per standard lug box, or equivalent quantity of nectarines in other containers or in bulk so handled by such handler during such fiscal period.

(c) *Reserve.* Unexpended assessment funds, in excess of expenses incurred during the fiscal period ending February 28, 1965, shall be carried over as a reserve in accordance with the applicable provisions of § 916.42 of said marketing agreement and order.

It is hereby found that good cause exists for not postponing the effective time of this action until 30 days after publication in the FEDERAL REGISTER (5 U.S.C. 1001–1011) in that (1) the relevant provisions of said marketing agreement and this part require that the rate of assessment fixed for a particular fiscal period shall be applicable to all assessable nectarines from the beginning of such period; and (2) the current fiscal period began on March 1, 1964, and the rate of assessment herein fixed will automatically apply to all assessable nectarines beginning with such date.

Terms used in the marketing agreement and order shall, when used herein, have the same meaning as is given to the respective term in said marketing agreement and order, and "standard lug box" shall mean the No. 26 standard lug box set forth in § 828.4 of the Agricultural Code of California.

(Secs. 1–19, 48 Stat. 31, as amended; 7 U.S.C. 601–674)

Dated: June 9, 1964.

PAUL A. NICHOLSON,
Deputy Director, Fruit and Vegetable Division, Agricultural Marketing Service.

[F.R. Doc. 64–5873; Filed, June 12, 1964; 8:47 a.m.]

[965.306, Amdt. 3]

PART 965—TOMATOES GROWN IN THE LOWER RIO GRANDE VALLEY IN TEXAS

Limitation of Shipments

Findings. (a) Pursuant to Marketing Order No. 965 (7 CFR Part 965), regulating the handling of tomatoes grown in the Counties of Cameron, Hidalgo, Starr and Willacy in Texas (Lower Rio Grande Valley), effective under the applicable provisions of the Agricultural Marketing Agreement Act of 1937, as amended (7 U.S.C. 601 et seq.), and upon the basis of recommendations and information submitted by the Texas Valley Tomato Committee, established pursuant to the said marketing order, and other available information, it is hereby found that the amendment to the limitation of shipments regulations, hereinafter set forth, will tend to effectuate the declared policy of the act.

(b) It is hereby found that it is impracticable and contrary to the public interest to give preliminary notice, or engage in public rule making procedure, and that good cause exists for not postponing the effective date of this amendment until 30 days after publication in the FEDERAL REGISTER (5 U.S.C. 1003) in that (1) the time intervening between the date when information upon which this regulation is based became available and the time when this amendment must become effective in order to effectuate the declared policy of the act is insufficient since the marketing season of the 1963-64 Lower Valley tomato crop has begun, (2) regulations have been issued under the order since 1959, so compliance with this regulation will not require any special preparation on the part of handlers, (3) information regarding the committee's recommendation has been made available to producers and handlers in the production area, and (4) this amendment relieves restrictions on the handling of tomatoes grown in the production area.

Order, as amended. In § 965.306 (29 F.R. 5636, 7143, 7376) the introductory paragraph, paragraph (a)(1), and paragraph (g) are amended to read as follows:

§ 965.306 Limitation of Shipments.

Except as otherwise provided in this section, during the period June 11, 1964, through July 15, 1964, the following regulations shall be effective with respect to all varieties of tomatoes handled, except cerasiform type tomatoes commonly referred to as cherry tomatoes, as defined in § 965.5 of Order No. 965, and no person shall handle such tomatoes or cause such tomatoes to be handled unless they are inspected and certified as required by paragraph (b) of this section, and meet the requirements of paragraph (a) of this section. Elongated types of tomatoes, commonly referred to as pear shaped tomatoes and including but not limited to San Marzano, Red Top, and Roma varieties are not subject to the requirements of subparagraphs (2) and (3) of paragraph (a) of this section.

(a) *Requirements*—(1) *Minimum grade.* U.S. No. 3, or better, grade, except that an additional 5 percent tolerance will be allowed for tomatoes which fail to meet such grade only because of very serious insect damage affecting stem scars. Individual packages in any lot may have not more than double the tolerance specified.

* * * * *

(g) *Definition.* Grade, size, and color: The terms "U.S. No. 2," "U.S. No. 3," "green," "breakers," and "very serious damage" shall have the same meanings as set forth in the United States Standards for Fresh Tomatoes (§§ 51.1855–51.1877 of this title; 22 F.R. 4528 as amended, 26 F.R. 8559), including the tolerances set forth therein; and the application for tolerance for size shall be as set forth in § 51.1861 of such standards. Other terms used in this section shall have the same meaning as when used in this part (Marketing Order No. 965).

* * * * *

(Secs. 1–19, 48 Stat. 31, as amended; 7 U.S.C. 601 et seq.)

Dated, June 11, 1964, to become effective June 11, 1964.

PAUL A. NICHOLSON,
Deputy Director,
Fruit and Vegetable Division.

[F.R. Doc. 64–5965; Filed, June 12, 1964; 8:50 a.m.]

[980.202, Amdt. 3]

PART 980—VEGETABLES; IMPORT REGULATIONS

Tomatoes

Pursuant to the requirement contained in § 608e-1 of the Agricultural Marketing Agreement Act of 1937, as amended (secs. 1–19, 48 Stat. 31, as amended; 7 U.S.C. 601 et seq.), § 980.202 *Tomato Import Regulation No. 9* (29 F.R. 6001, 7143, 7377), is hereby amended as set forth below.

Order, as amended. Amend paragraph (a)(1) and subparagraph (g)(1) in § 980.202 *Tomato Import Regulation No. 9*, to read as follows:

(a) *Minimum grade and size requirements*—(1) *Grade.* U.S. No. 3, or better, grade, except that an additional 5 percent tolerance will be allowed for tomatoes which fail to meet such grade only because of very serious insect damage affecting stem scars. Individual packages in any lot may have not more than double the tolerance specified.

* * * * *

(g) *Definitions.* (1) The terms "U.S. No. 3" and "U.S. No. 2" and "very serious damage" shall have the same meaning as set forth in the United States Standards for Fresh Tomatoes (§§ 51.1855 to 51.1877, inclusive, of this title), including the tolerances set forth therein.

* * * * *

This amendment accords with simultaneous amendment to the limitation of shipments regulation effective on domestic shipments of tomatoes (§ 965.306, Amendment No. 3) under Marketing Order No. 965 (7 CFR Part 965), regulating the handling of tomatoes grown in the Lower Rio Grande Valley in Texas, and relieves restrictions on the importation of tomatoes from the effective date hereof through July 15, 1964. Accordingly notice of rule making and publication procedure hereon are unnecessary and impractical and there is no reason to postpone the effective date beyond June 11, 1964 (5 U.S.C. 1003).

(Secs. 1–19, 48 Stat. 31, as amended; 7 U.S.C. 601 et seq.)

Dated, June 11, 1964, to become effective June 11, 1964.

PAUL A. NICHOLSON,
Deputy Director,
Fruit and Vegetable Division.

[F.R. Doc. 64–5966; Filed, June 12, 1964; 8:50 a.m.]

Chapter XIV—Commodity Credit Corporation, Department of Agriculture

SUBCHAPTER B—LOANS, PURCHASES, AND OTHER OPERATIONS

[C.C.C. Grain Price Support Regs. 1964 Crop Grain Sorghum Supp.]

PART 1421—GRAINS AND SIMILARLY HANDLED COMMODITIES

Subpart—1964 Crop Grain Sorghum Loan and Purchase Program

The General Regulations Governing Price Support for the 1964 and subsequent crops (29 F.R. 2686) issued by the Commodity Credit Corporation which contain regulations of a general nature with respect to price support loan and purchase operations are supplemented for the 1964-crop of grain sorghum as follows:

Sec.
1421.2521 Purpose.
1421.2522 Availability.
1421.2523 Compliance requirements.
1421.2524 Eligible grain sorghum.
1421.2525 Determination of quality.
1421.2526 Determination of quantity.
1421.2527 Warehouse receipts.
1421.2528 Service charges.
1421.2529 Warehouse charges.
1421.2530 Maturity of loans.
1421.2531 Support rates.

AUTHORITY: The provisions of this subpart issued under sec. 4, 62 Stat. 1070 as amended; 15 U.S.C. 714b. Interpret or apply sec. 5, 62 Stat. 1072, secs. 105, 401, 63 Stat. 1051 as amended; 15 U.S.C. 714c, 7 U.S.C. 1421, 1441.

§ 1421.2521 Purpose.

This subpart contains additional program provisions which, together with the applicable provisions of the General Regulations Governing Price Support for the 1964 and Subsequent Crops and any amendments thereto, apply to loans and purchases for 1964 crop grain sorghum. (Such regulations are referred to herein as "General Regulations".)

§ 1421.2522 Availability.

Producers desiring Price Support must file an application not later than January 31, 1965. Loans will be available through February 28, 1965.

§ 1421.2523 Compliance requirements.

(a) A producer shall not be eligible for a loan or purchase unless he is eligible to receive a price support payment on grain sorghum of the 1964 crop under the 1964 and 1965 Feed Grain Program Regulations (29 F.R. 590 and any amendments thereto) on the farm on which the grain sorghum tendered for loan or purchase is produced, except as provided below in this section.

(b) The requirements of this section shall not be applicable to grain sorghum produced in Alaska or in any other area of the United States where the 1964 and 1965 Feed Grain Program is not applicable on grain sorghum of the 1964 crop and price support payments are not made on such grain sorghum because of an emergency created by drought or other disaster or in order to prevent or alleviate a shortage in the supply of the commodity.

(c) A producer shall not be considered ineligible for a loan or purchase on grain sorghum because he has not received a price support payment on grain sorghum of the 1964 crop under the 1964 and 1965 Feed Grain Program Regulations if he would be eligible for a payment except for the fact that (1) he has declined a price support payment or (2) the grain sorghum has been produced on land owned by the Federal Government and leased subject to restrictions prohibiting the receipt of Federal payments for diversion of acreage but not prohibiting the production of grain sorghum.

§ 1421.2524 Eligible grain sorghum.

(a) *General.* Grain sorghum must be merchantable for food or feed or for other uses, as determined by CCC, and must not contain mercurial compounds or other substances poisonous to man or animals in order to be eligible for price support.

(b) *Warehouse stored loan grade requirements.* Grain sorghum to be placed under a Warehouse Storage Loan must also meet the following requirements:

(1) The grain sorghum must be of any class grading No. 4 or better, except for moisture, and in addition may carry the special grade designation "Smutty."

(2) Grain sorghum must not grade "Weevily" unless the warehouse receipt is accompanied by a supplemental certificate which indicates the warehouseman will deliver grain sorghum which does not contain such designation and which is otherwise of an eligible grade and quality. When the warehouse receipt shows "Weevily" the grade, grading factors, and the quantity shown on the supplemental certificate must be as specified in § 1421.2527(c); (3) grain sorghum cannot contain over 14 percent moisture unless the warehouse receipt is accompanied by a supplemental certificate which indicates the warehouseman will deliver grain sorghum containing not over 14 percent moisture and which is otherwise of an eligible quality. The grade, grading factors and the quantity shown on the supplemental certificate must be as specified in § 1421.2527(c).

§ 1421.2525 Determination of quality.

The class, grade, grading factors and all other quality factors shall be based on the Official Grade Standards of the United States for grain sorghum, whether or not such determinations are made on the basis of an official inspection.

§ 1421.2526 Determination of quantity.

When the quantity is determined by weight, a unit of 100 pounds shall be 100 pounds of grain sorghum free of dockage.

(a) *In warehouse.* The quantity of grain sorghum on which a warehouse storage loan shall be made and the quantity delivered to or acquired by CCC in an approved warehouse shall be the net weight specified on the warehouse receipt or on the supplemental certificate, if applicable. If the grain sorghum has been dried or blended to reduce the moisture content, the quantity specified on the warehouse receipt or the supplemental certificate, if applicable, shall represent the quantity after drying or blending, and such quantity shall reflect a minimum shrink in the receiving weight of 1.2 times the percentage difference of the moisture content of the grain sorghum, when received, and 14 percent.

(b) *On farm.* The quantity eligible to be placed under farm storage loan shall be determined in accordance with § 1421.67 of the General Regulations. The quantity acquired by CCC shall be determined by weight. In determining the quantity of sacked grain sorghum by weight, a deduction of ¾ of a pound for each sack shall be made.

(c) *Dockage.* When the quantity is determined by weight, the percentage of dockage shall be determined and the weight of such dockage shall be deducted from the gross weight in determining the net quantity.

§ 1421.2527 Warehouse receipts.

Warehouse receipts tendered to CCC in connection with a loan or purchase must meet the requirements of this section.

(a) *Separate receipt.* A separate warehouse receipt must be submitted for each grade and class of grain sorghum.

(b) *Entries.* Each warehouse receipt, or the warehouseman's supplemental certificate (in duplicate) properly identified with the warehouse receipt, must show: (1) Gross and net weight, (2) class, (3) grade (including special grades), (4) test weight, (5) moisture, (6) dockage, (7) any other grading factor(s) when such factor(s) and not test weight determine the grade and (8) whether the grain sorghum arrived by rail, truck or barge.

(c) *Where warehouse receipt shows "Weevily" or moisture over 14 percent.* Where a warehouse receipt tendered for loan shows that the grain sorghum grades "Weevily" or contains over 14 percent moisture, the warehouse receipt must be accompanied by a supplemental certificate as provided in § 1421.2524(b) in order for the grain sorghum to be eligible for price support. The grade, grading factors, and the quantity to be delivered must be shown on the supplemental certificate as follows: (1) When the warehouse receipt shows "Weevily" and the grain sorghum has been conditioned to correct the "Weevily" condition, the supplemental certificate must show the same grade without the "Weevily" designation and the same grading factors and quantity as shown on the warehouse receipt; (2) when the warehouse receipt shows moisture over 14 percent and the grain sorghum has been dried or blended, the supplemental certificate must show the grade, grading factors, and quantity after drying or blending the grain sorghum to a moisture content of not over 14 percent. The quantity shown on the Supplemental Certificate shall reflect a drying or blending shrink as specified in § 1421.2526; (3) the supplemental certificate must state that no lien for processing will be claimed by the warehouseman from Commodity Credit Corporation or any subsequent holder of the warehouse receipt; (4) in the case of conditions specified in subparagraphs (1) and (2) of this paragraph, the grade, grading factors, and the quantity shown on the supplemental certificate shall supersede the entries for such items on the warehouse receipt.

(d) *Liens.* The warehouse receipts may be subject to liens for warehouse charges only to the extent indicated in § 1421.2529.

(e) *Freight bill requirements.* Warehouse receipts representing grain sorghum which has been shipped by rail or water from a country shipping point to a designated terminal point, or shipped by rail or water from a country shipping point to a storage point and stored in transit to a designated terminal point, must be accompanied by registered freight bills or by a certificate containing similar information. These registered freight bills or certificates must be representative as to origin and date of movement of the grain sorghum and must reflect the total freight from origin to the designated terminal point including penalty for out-of-line haul, if any. The form of these certificates shall be prescribed by the ASCS commodity office and shall be signed by the warehouseman and may be made a part of the supplemental certificate.

§ 1421.2528 Service charges.

A charge of one cent per hundredweight will be made for the quantity acquired by CCC and such charge shall be handled in accordance with § 1421.60(b).

§ 1421.2529 Warehouse charges.

(a) *Handling and storage liens.* Warehouse receipts and the grain sorghum represented thereby stored in approved warehouses operating under the Uniform Grain Storage Agreement may be subject to liens for warehouse handling and storage charges at not to exceed the Uniform Grain Storage Agreement rates from the date the grain sorghum is deposited in the warehouse for storage. Warehouse receipts and the grain sorghum represented thereby stored in approved warehouses operated by Eastern common carriers may be subject to liens for warehouse elevation (receiving and delivering) and storage charges from the date of deposit at rates approved by the Interstate Commerce Commission. In no event shall a warehouseman be entitled to satisfy the lien by sale of the grain sorghum when CCC is holder of the warehouse receipt.

(b) *Deduction of storage charges—UGSA warehouses.* The table shown below provides the deduction for storage charges to be made from the amount of the loan or purchase price in the case of grain sorghum stored in an approved warehouse operated under the Uniform Grain Storage Agreement. Such deduction shall be based on entries shown on the warehouse receipts. If written evidence is submitted with the warehouse receipt that all warehouse charges except receiving and loading out charges have been prepaid through the applicable loan maturity date, no storage deductions shall be made. If such written evidence is not submitted, the date to be used for computing the storage deduction on grain sorghum stored in approved warehouses operating under the Uniform Grain Storage Agreement shall be the latest of the following: (1) The date of deposit, (2) the date storage charges start, or (3) the day following the date through which the storage charges have been paid. If none of the foregoing dates is shown, the date of the warehouse receipt shall be used.

Schedule of Deductions for Storage Charges for Maturity Date of No Later Than March 31, 1965

Amount of deduction (cents per hundredweight):	*Date the storage charges start*
21	Prior to May 28, 1964.
20	May 28–June 11, 1964.
19	June 12–June 26, 1964.
18	June 27–July 11, 1964.
17	July 12–July 26, 1964.
16	July 27–Aug. 10, 1964.
15	Aug. 11–Aug. 25, 1964.
14	Aug. 26–Sept. 9, 1964.
13	Sept. 10–Sept. 24, 1964.
12	Sept. 25–Oct. 9, 1964.
11	Oct. 10–Oct. 24, 1964.
10	Oct. 25–Nov. 8, 1964.
9	Nov. 9–Nov. 23, 1964.
8	Nov. 24–Dec. 8, 1964.
7	Dec. 9–Dec. 23, 1964.
6	Dec. 24, 1964–Jan. 7, 1965.
5	Jan. 8–Jan. 22, 1965.
4	Jan. 23–Feb. 6, 1965.
3	Feb. 7–Feb. 21, 1965.
2	Feb. 22–Mar. 8, 1965.
1	Mar. 9–Mar. 31, 1965.

(c) *Deduction of storage charges—Eastern common carriers.* In the case of grain sorghum stored in an approved warehouse operated by an Eastern common carrier, there shall be deducted in computing the loan or purchase price the amount of the approved tariff rate for storage (not including elevation), which will accumulate from the date of the deposit through the applicable maturity date unless written evidence is submitted with the warehouse receipt that such charges have been prepaid. The county office shall request the ASCS commodity office to determine the amount of such charges. Where the producer presents evidence showing the elevation charges have been prepaid, the amount of the storage charges to be deducted shall be reduced by the amount of the elevation charges prepaid by the producer.

§ 1421.2530 Maturity of loans.

Loans mature on demand but not later than March 31, 1965.

§ 1421.2531 Support rates.

Basic support rates per hundredweight for grain sorghum grading No. 2 or better and containing not over 14 percent moisture will be a part of this Section to be issued at a later date. Farm stored loans will be made at the applicable basic support rate adjusted only for the discount for Weed Control Laws where applicable. Warehouse stored loans, farm stored loan settlements and purchases shall be on the basis of the applicable basic support rate adjusted by the discounts shown in paragraph (d) of this section and such other discounts as may be established by CCC applicable to the grade and quality of the grain sorghum on which the loan or settlement is made.

(a) *Support rates at designated terminal markets.* (1) The basic support rates established for designated terminal markets apply to grain sorghum shipped on a domestic interstate freight rate basis. The basic support rate at the designated terminal market for any grain sorghum shipped at other than the domestic interstate freight rate shall be reduced by the difference between the freight rate paid and the domestic interstate freight rate.

(2) The basic support rates established for designated terminal markets also apply to grain sorghum which has been shipped by rail or water from a country shipping point to one of the designated terminal markets, as evidenced by paid freight bills duly registered for transit privileges. In the event the amount of paid-in freight is insufficient to guarantee the minimum proportional domestic interstate freight rate, if any, from the terminal market to a recognized market determined by the appropriate ASCS commodity office, there shall be deducted from the applicable basic support rate the difference between the amount of freight actually paid in and the amount required to be paid in to guarantee outbound movement at the minimum proportional domestic interstate freight rate. If the grain sorghum is stored at any designated terminal market and neither registered freight bills nor registered freight certificates are presented, the basic support rate shall be reduced by the actual amount of paid-in freight required to guarantee the proportional outbound rate from the terminal market to a recognized market determined by the appropriate ASCS commodity office.

(3) In determining the support rate for grain sorghum received by truck and stored at any designated terminal market there shall be deducted from the applicable basic support rate, the actual amount of paid-in freight required to guarantee the proportional outbound rate from the terminal market to a recognized market determined by the appropriate ASCS commodity office, plus 6 cents per hundredweight.

(4) Notwithstanding the foregoing provisions of this paragraph, in determining the support rate for grain sorghum shipped by rail or water and stored at any of the following terminal markets there shall be deducted from the applicable basic support rate, the transportation cost, if any, as determined by the appropriate ASCS commodity office, for moving the grain sorghum to a tidewater facility located within the same switching limits:

Long Beach, Los Angeles, Oakland, San Francisco, Stockton, and Wilmington, California.

Baton Rouge and New Orleans, Louisiana.

Astoria and Portland, Oregon.

Beaumont, Corpus Christi, Galveston, Houston, and Port Arthur, Texas.

Kalama, Longview, Seattle, Tacoma, and Vancouver, Washington.

(5) Notwithstanding the foregoing provisions of this paragraph, in determining the support rate for grain sorghum received by truck and stored at any of the terminal markets listed in subparagraph (4) of this paragraph there shall be deducted from the applicable basic support rate an amount of 6 cents per hundredweight, plus the transportation cost, if any, as determined by the appropriate ASCS commodity office, for moving the grain sorghum to a tidewater loading facility located within the same switching limits.

(b) *Support rates for grain sorghum in approved warehouse storage at other than designated terminal markets.* In determining the support rate for grain sorghum which is shipped by rail or water and which is stored in approved warehouses (other than those situated in the designated terminal markets) there shall be deducted from the basic support rate for the appropriate designated terminal market, as determined by CCC, an amount equal to the transit balance, if any, of the through-freight rate from the point of origin for such grain sorghum to such terminal market: *Provided,* That on any grain sorghum shipped at other than the domestic interstate freight rate, the basic support rate shall be further reduced by the difference between the freight rate paid and the domestic interstate freight rate from the point of origin of such grain sorghum to the point of destination or appropriate terminal market: *And provided further,* That in the case of grain sorghum stored at any railroad transit point, taking a penalty by reason of out-of-line movement to the appropriate designated market, or for any other reason, there shall be added to such transit balance an amount equal to any out-of-line costs or other cost incurred in storing grain sorghum in such position.

(c) *Basic county support rates.* (1) The applicable support rate for farm-storage loans and for grain stored in approved country warehouse-storage, except as otherwise provided in paragraph (b) of this section and subparagraph (2) of this paragraph will be determined from the basic county support rate established for the county in which the grain sorghum is stored.

(2) If two or more approved warehouses are located in the same or adjoining towns, villages, or cities, having the same domestic interstate freight rate, such towns, villages, or cities shall be deemed to constitute one shipping point and the same basic support rate shall apply even though such warehouses are not all located in the same county. Such support rate shall be the highest support rate of the counties involved.

(d) *Discounts.* The basic support rate shall be adjusted as applicable by discounts as follows:

Reason:	*Discount (cents per hundredweight)*
Class-Mixed Grain Sorghum	3
Grade:	
No. 3 (Not over 14 percent moisture)	3
No. 4 (Not over 14 percent moisture)	5
Smutty	5
Weed control laws (See § 1421.74)	15

Note: Discounts are cumulative except only one grade discount shall be applied.

Effective date. Upon publication in the FEDERAL REGISTER.

Signed at Washington, D.C., on June 10, 1964.

E. A. JAENKE,
Acting Executive Vice President,
Commodity Credit Corporation.

[F.R. Doc. 64-5901; Filed, June 12, 1964; 8:49 a.m.]

PART 1443—OILSEEDS

Subpart—1964-Crop Supplement to Cottonseed Purchase Program Regulations

The Cottonseed Purchase Program Regulations issued by Commodity Credit Corporation and containing the regulations of a general nature with respect to purchase operations for cottonseed are supplemented for 1964-crop cottonseed as follows:

Sec.
1443.2060 Purpose.
1443.2061 Purchase price.

AUTHORITY: The provisions of this subpart issued under sec. 4, 5, 62 Stat. 1070, as amended, secs. 301, 401, 63 Stat. 1053, 1054, as amended, sec. 601, 70 Stat. 212; 15 U.S.C. 714 b and c, 7 U.S.C. 1447, 1421, 1446d.

§ 1443.2060 Purpose.

This subpart contains basic purchase prices for cottonseed purchased from producers and from participating ginners which, together with the provisions of the Cottonseed Purchase Program Regulations issued by Commodity Credit Corporation, and any amendments thereto, apply to purchases of 1964-crop cottonseed.

§ 1443.2061 Purchase price.

(a) *Price to producers.* Any direct purchases of cottonseed by Commodity Credit Corporation from producers will be made at the rate of $44 per gross ton for basis grade (100) cottonseed, with premiums and discounts for other grades equal to the same percentage of such price as the percentage by which the grade of cottonseed purchased exceeds or is less than 100. The price per ton thus computed shall be rounded to the nearest multiple of ten cents.

(b) *Price to ginners.* Any purchases of cottonseed by Commodity Credit Corporation from participating ginners will be made at the rate of $48 per net ton for basis grade (100) cottonseed, with premiums and discounts for other grades equal to the same percentage of such price as the percentage by which the grade of cottonseed purchased exceeds or is less than 100.

Effective date. This subpart shall be effective upon publication in the FEDERAL REGISTER.

Signed at Washington, D.C., on June 10, 1964.

E. A. JAENKE,
Acting Executive Vice President,
Commodity Credit Corporation.

[F.R. Doc. 64-5902; Filed, June 12, 1964; 8:49 a.m.]

Title 12—BANKS AND BANKING

Chapter I—Bureau of the Comptroller of the Currency, Department of the Treasury

PART 1—INVESTMENT SECURITIES REGULATION

School Refunding Bonds, Broward County, Fla.

§ 1.141 School Refunding Bonds, Broward County, Florida.

(a) *Request.* The Comptroller of the Currency has been requested to rule that the $12,350,000 School Refunding Bonds, Series of 1963, of Special Tax School District Number One, Broward County, Florida, are eligible for purchase, dealing in, underwriting and unlimited holding by National Banks under paragraph Seventh of 12 U.S.C. 24.

(b) *Opinion.* (1) Special Tax School District Number One, Broward County, Florida, is a body politic exercising governmental powers relating to the administration and operation of all public schools in Broward County and having the power to tax through levy and collection of a direct annual tax, without limitation as to rate and amount, upon all taxable property within the school district for the purpose of paying principal of and interest on bonds which it may issue. The area of the school district is coterminous with that of Broward County.

(2) The proceeds from the sale of these bonds will be used on June 1, 1966, to refund an outstanding 1956 series. Until this refunding takes place, the proceeds will be invested in direct obligations of the United States which are expected to provide income sufficient for debt service requirements. During this initial period, the proceeds of the 1963 bonds and the direct obligations of the United States in which they are invested will be the sole security for the 1963 bonds. Upon retirement of the outstanding 1956 bonds, the 1963 bonds will become general obligations of the school district for the payment of which the full faith, credit and taxing power of the school district has been pledged. The 1963 bonds will thus be supported at all times by resources sufficient to justify full faith and credit.

(c) *Ruling.* Following the principles and definitions set forth in paragraphs (c), (d), and (e) of § 1.3, it is our conclusion that the School Refunding Bonds, Series of 1963, of Special Tax School District Number One, Broward County, Florida, are eligible for purchase, dealing in, underwriting and unlimited holding under paragraph Seventh of 12 U.S.C. 24.

Dated: June 8, 1964.

[SEAL] JAMES J. SAXON,
Comptroller of the Currency.

[F.R. Doc. 64-5881; Filed, June 12, 1964; 8:47 a.m.]

Title 14—AERONAUTICS AND SPACE

Chapter I—Federal Aviation Agency

SUBCHAPTER D—AIRMEN [NEW]

[Reg. Docket 1901; Amdt. 61-10]

PART 61—CERTIFICATION: PILOTS AND FLIGHT INSTRUCTORS [NEW]

Student Pilot Solo Requirements in Gyroplanes

This amendment authorizes student pilots to solo single-place gyroplanes without meeting all of the student pilot solo flight requirements of § 61.63.

Section 61.63 requires a student pilot, before soloing a rotorcraft, to have "flight instruction (from an appropriately rated flight instructor) in preparatory and flight procedures such as preflight inspection, starting, warming up, and operating and stopping the engine; taxiing, takeoff, hovering (helicopter class only), landing, and parking; in traffic pattern procedures; and in emergency procedures including engine failure;". In the case of a single-place gyroplane, the parenthetical expression "(from an appropriately rated flight instructor)" has created difficulty since there are not any two-place gyroplanes available in which to give flight instruction. Flight instruction in helicopters, which are of the rotorcraft category, would satisfy the regulatory requirement of the flight instructor being "appropriately rated", but the flight characteristics of helicopters and gyroplanes are different in fundamental respects and the flight instructor would still be obliged to use some means other than flight instruction in a helicopter to make a determination of the applicant's ability to solo gyroplanes. Therefore, the requirements are impractical, and burdensome upon a holder of a student pilot certificate who wishes to solo single-place gyroplanes.

To answer the problem, the Agency issued Special Regulation SR-451, effective June 12, 1962, to expire June 12, 1964. The expiration date of SR-451 was established since it was expected that two-place gyroplanes would be sufficiently common for student pilots to obtain flight instruction. However, the production of two-place gyroplanes has not materialized as expected. Therefore, by this amendment the Agency is amending Part 61 [New] of the Federal Aviation Regulations to incorporate the essential provisions of SR-451 into § 61.63. A certificated flight instructor with either a rotorcraft or airplane category rating will be permitted to endorse a student pilot for solo flight in single-place gyroplanes if the student pilot has satisfied the other requirements for solo flight and the flight instructor has observed the student pilot competently make at least three takeoffs and landings to a full stop in a gyroplane or gyroglider attached by a towline to a vehicle on the surface. Agency review showed that operations conducted under the privileges of SR-451 have been accomplished without adverse effect on safety.

Since this amendment imposes no additional burden on any person, and continues in effect the substance of a needed rule which is about to expire, the Agency for good cause has found that compliance with the notice and public procedure provisions of the Administrative Procedure Act is unnecessary and impractical and it may be made effective in less than 30 days.

In consideration of the foregoing, § 61.63 of Part 61 [New] of Chapter I of Title 14 of the Code of Federal Regulations is amended, effective June 12, 1964, by redesignating paragraph (b) as paragraph (c) and adding a new paragraph (b) to read as follows:

§ 61.63 Requirements for solo flight.

* * * * *

(b) In the case of a single-place gyroplane, the holder of a student pilot certificate meets the requirements of paragraph (a) (2) (ii) and (3) of this section if—

(1) He receives instruction in the ground operating procedures specified in paragraph (a) (2) (ii) from the holder of a flight instructor certificate with either an airplane or rotorcraft category rating on that certificate; and

(2) That flight instructor—

(i) Certifies in the student pilot's logbook that he has observed him competently make at least three landings and takeoffs to a full stop in a gyroplane or gyroglider towed by a line attached to a vehicle on the surface; and

(ii) Determines that the student has complied with this section, is otherwise able to make solo flights, and endorses the student pilot's certificate for solo flight in that make and model of aircraft.

* * * * *

(Secs. 313(a), 601, 602 of the Federal Aviation Act of 1958; 49 U.S.C. 1354, 1421, 1422)

Issued in Washington, D.C., on June 9, 1964.

N. E. HALABY,
Administrator.

[F.R. Doc. 64-5789; Filed, June 12, 1964; 8:45 a.m.]

SUBCHAPTER E—AIRSPACE [NEW]

[Airspace Docket 63-WE-53]

PART 71—DESIGNATION OF FEDERAL AIRWAYS, CONTROLLED AIRSPACE AND REPORTING POINTS [NEW]

Revocation of Federal Airway Segments

On March 11, 1964, a notice of proposed rule making was published in the FEDERAL REGISTER (29 F.R. 3236) stating that the Federal Aviation Agency proposed to revoke the segments of Amber Federal airway No. 1 from Red Bluff, Calif., to Eugene, Oreg., and from Portland, Oreg., to Seattle, Wash.

Interested persons were afforded an opportunity to participate in the rule making through submission of comments. All comments received were favorable.

The substance of the proposed amendment having been published and for the reasons stated in the Notice, § 71.105 (29 F.R. 1006, 4908) is amended as follows: In A-1 "From the Red Bluff, Calif., RR via the Fort Jones, Calif., RR; Medford, Oreg., RR; Eugene, Oreg., RR; Portland, Oreg., RR; Toledo, Wash., RR; Seattle, Wash., RR;" is deleted and "From Eugene, Oreg., RR to the Portland, Oreg., RR. From Seattle, Wash., RR via the" is substituted therefor.

This amendment shall become effective 0001 e.s.t., August 20, 1964.

(Sec. 307(a), 72 Stat. 749; 49 U.S.C. 1348)

Issued in Washington, D.C., on June 5, 1964.

H. B. HELSTROM,
Acting Chief, Airspace Regulations and Procedures Division.

[F.R. Doc. 64-5850; Filed, June 12, 1964; 8:46 a.m.]

[Airspace Docket 64-CE-4]

PART 71—DESIGNATION OF FEDERAL AIRWAYS, CONTROLLED AIRSPACE, AND REPORTING POINTS [NEW]

Designation of Federal Airway Segment

On March 14, 1964, a notice of proposed rule making was published in the FEDERAL REGISTER (29 F.R. 3404) stating that the Federal Aviation Agency proposed to designate a segment of VOR Federal airway No. 133 from Traverse City, Mich., via Escanaba, Mich., to Marquette, Mich.

Interested persons were afforded an opportunity to participate in the rule making through submission of comments. All comments received were favorable.

The substance of the proposed amendment having been published and for the reason stated in the Notice, § 71.123 (29 F.R. 1009) is amended as follows: In V-133 "to Traverse City, Mich." is deleted and "Traverse City, Mich.; Escanaba, Mich.; to Marquette, Mich." is substituted therefor.

This amendment shall become effective 0001 e.s.t., August 20, 1964.

(Sec. 307(a), 72 Stat. 749; 49 U.S.C. 1348)

Issued in Washington, D.C., on June 5, 1964.

H. B. HELSTROM,
Acting Chief, Airspace Regulations and Procedures Division.

[F.R. Doc. 64-5848; Filed, June 12, 1964; 8:45 a.m.]

[Airspace Docket 64-SW-18]

PART 71—DESIGNATION OF FEDERAL AIRWAYS, CONTROLLED AIRSPACE, AND REPORTING POINTS [NEW]

Alteration of Transition Area

The purpose of this amendment to Part 71 [New] of the Federal Aviation Regulations is to revoke the portion of the Las Vegas, N. Mex., transition area based upon the Las Vegas radio range. The Las Vegas radio range is scheduled to be decommissioned on approximately June 25, 1964, resulting in the cancellation of the range approach. Therefore the requirement for the controlled airspace to protect the range approach will cease with the decommissioning of the range.

Since this amendment imposes no additional burden on any person, notice and public procedure hereon are unnecessary and the amendment may be made effective without regard to the 30-day statutory period preceding effectiveness.

In consideration of the foregoing, Part 71 [New] of the Federal Aviation Regulations is amended, effective June 25, 1964, as hereinafter set forth. In § 71.181 (29 F.R. 1160) the Las Vegas, N. Mex., transition area is amended as follows: Delete "(latitude 35°39′25″ N., longitude 105°08′35″ W.), within 2 miles each side of the Las Vegas RR SW course, extending from the 8-mile radius area to 8 miles SW of the RR;" and substitute "(Lat. 35°39′25″ N., Long. 105°08′35″ W.)," therefor.

(Sec. 307(a) of the Federal Aviation Act of 1958; 49 U.S.C. 1348)

Issued in Washington, D.C. on June 5, 1964.

H. B. HELSTROM,
Acting Chief, Airspace Regulations and Procedures Division.

[F.R. Doc. 64-5851; Filed, June 12, 1964; 8:46 a.m.]

[Airspace Docket 63-EA-77]

PART 71—DESIGNATION OF FEDERAL AIRWAYS, CONTROLLED AIRSPACE, AND REPORTING POINTS [NEW]

PART 73—SPECIAL USE AIRSPACE [NEW]

Designation of Restricted Area and Alteration of Federal Airways

On February 28, 1964, a notice of proposed rule making was published in the FEDERAL REGISTER (29 F.R. 2791) stating that the Federal Aviation Agency proposed to designate a restricted area near Romulus, N.Y.

Interested persons were afforded an opportunity to participate in the rule making through submission of comments. All comments received were favorable.

In consideration of the foregoing, Parts 73 and 71 [New] of the Federal Aviation Regulations are amended, effective 0001 e.s.t., August 20, 1964, as hereinafter set forth.

1. In § 73.52 (29 F.R. 1267) the following is added:

R-5207 Romulus, N.Y.

Boundaries. A circular area with a radius of 1,350 feet centered at latitude 42°46′59″ N., longitude 76°53′06″ W.

Designated altitudes. Surface to 2,000 feet MSL.

Time of designation. 0730 to 1815 local time, Monday through Friday.

Using agency. Commanding Officer, Seneca Army Depot, Romulus, N.Y.

2. Section 71.123 (29 F.R. 1009, 3225, 4671) is amended as follows: In Federal airways V-14 and V-34 add, "The airspace within R-5207 is excluded."

(Sec. 307(a) of the Federal Aviation Act of 1958; 49 U.S.C. 1348)

Issued in Washington, D.C., on June 5, 1964.

Clifford P. Burton,
Acting Director,
Air Traffic Service.

[F.R. Doc. 64-5852; Filed, June 12, 1964; 8:46 a.m.]

[Airspace Docket 64-WA-35]

PART 75—ESTABLISHMENT OF JET ROUTES [NEW]

Alteration, Correction

On June 2, 1964, Federal Register Document No. 64-5444, was published in the Federal Register (29 F.R. 7145) amending Part 71 [New] of the Federal Aviation Regulations by altering VOR Federal airway No. 216 from Peck, Mich., direct to the new Kleinburg, Ontario, Canada, VOR. These actions are to become effective 0001 e.s.t., July 2, 1964.

Subsequent to publication of the document, it has been determined that the United States portion of Canadian High Level airway No. 546/J-546 also should be realigned from Peck direct to Kleinburg. Such action is taken herein. Since this change is minor in nature and imposes no undue burden on any person, notice and public procedure hereon are unnecessary and the effective date as originally adopted may be retained.

In consideration of the foregoing, effective immediately, Federal Register Document No. 64-5444 (29 F.R. 7145) is amended as follows.

1. In the heading add: Part 75—Establishment of Jet Routes [New].

2. After the fourth paragraph of the text, add:

In § 75.100 (29 F.R. 1287) Jet Route No. 546 is amended to read "Jet Route No. 546 (Peck, Mich., to the United States/Canadian Border) (joins Canadian high level airway No. 546). From Peck, Mich., to the United States/Canadian Border via the Peck to Kleinburg, Ontario, direct radial."

(Sec. 307(a), 72 Stat. 749; 49 U.S.C. 1348)

Issued in Washington, D.C., on June 5, 1964.

H. B. Helstrom,
Acting Chief, Airspace Regulations
and Procedures Division.

[F.R. Doc. 64-5849; Filed, June 12, 1964; 8:45 a.m.]

Chapter III—Federal Aviation Agency

SUBCHAPTER C—AIRCRAFT REGULATIONS

[Reg. Docket 5001; Amdt. 746]

PART 507—AIRWORTHINESS DIRECTIVES

Dornier Model DO-28 Aircraft

A proposal to amend Part 507 of the Regulations of the Administrator to include an airworthiness directive requiring the changing of the electrical wiring on Dornier Model DO-28 aircraft was published in 29 F.R. 5349.

Interested persons have been afforded an opportunity to participate in the making of the amendment. No objections were received.

In consideration of the foregoing, and pursuant to the authority delegated to me by the Administrator (25 F.R. 6489), § 507.10(a) of Part 507 (14 CFR Part 507), is hereby amended by adding the following new airworthiness directive:

Dornier. Applies to all Model DO-28 aircraft up to and including Serial Number 3060.

Compliance required as indicated.

It has been found that the generator and battery relays remain inoperative with low battery voltage so that the electrical system remains without power supply. To correct this condition, accomplish the following:

Within the next 50 hours' time in service, change the electrical wiring as specified by Dornier Technical Bulletin 28-6 dated December 7, 1962.

(Dornier Technical Bulletin No. 28-6 dated December 7, 1962, covers this same subject.)

This amendment shall become effective July 13, 1964.

(Secs. 313(a), 601, 603; 72 Stat. 752, 775, 776; 49 U.S.C. 1354(a), 1421, 1423)

Issued in Washington, D.C., on June 8, 1964.

W. Lloyd Lane,
Acting Director,
Flight Standards Service.

[F.R. Doc. 64-5854; Filed, June 12, 1964; 8:46 a.m.]

[Reg. Docket No. 6014; Amdt. 745]

PART 507—AIRWORTHINESS DIRECTIVES

Lockheed Models 49 Through 1049H Series Aircraft

There have been several instances of cracks occurring in the nose landing gear retract cylinder rod terminal ends on Lockheed Models 49 through 1049H Series aircraft, one of which resulted in a failure. To correct this condition, an airworthiness directive is being issued to require inspection of the nose landing gear retract cylinder rod terminal ends and replacement of any parts found cracked.

As a situation exists which demands immediate adoption of this regulation, it is found that notice and public procedure hereon are impracticable and good cause exists for making this amendment effective upon publication in the Federal Register.

In consideration of the foregoing, and pursuant to the authority delegated to me by the Administrator (25 F.R. 6489), § 507.10(a) of Part 507 (14 CFR Part 507), is hereby amended by adding the following new airworthiness directive:

Lockheed. Applies to all Models 49, 149, 649, 649A, 749, 749A, 1049-54, 1049C, 1049D, 1049E, 1049G and 1049H Series aircraft.

Compliance required as indicated.

As a result of a number of reported cracks and one failure in the nose landing gear retract cylinder rod terminal end, accomplish the following:

(a) Aircraft on which the nose landing gear retract cylinder rod terminal ends, P/N's 404052 or 1005032 have accumulated 4,500 or more landings on the effective date of this AD, shall be inspected in accordance with (d) within 100 landings after the effective date of this AD, unless already accomplished within the last 250 landings, and thereafter at intervals not to exceed 350 landings. If the rod terminal end is reworked in accordance with (g) the reworked part shall be inspected in accordance with (d) within 700 landings after the rework is accomplished, and thereafter at intervals not to exceed 700 landings.

(b) Aircraft on which the nose landing gear retract cylinder rod terminal ends have accumulated less than 4,500 landings on the effective date of this AD, shall be inspected in accordance with (d) prior to the accumulation of 4,600 landings and thereafter at intervals not to exceed 350 landings. If the rod terminal end is reworked in accordance with (g), prior to accumulation of 4,500 landings the initial compliance with (d) is required prior to the accumulation of 5,200 landings and thereafter at intervals not to exceed 700 landings.

(c) For those operators maintaining records of hours' time in service in order to ascertain compliance with this AD, the number of landings required in (a) and (b) may be replaced with an equal number of hours' time in service. For those operators maintaining records of landings, in order to ascertain compliance with this AD where past records of landings are unavailable the number of landings prior to the effective date of this AD may be estimated by substituting one landing for each hour of time in service.

(d) Inspect the rod terminal end in the area between the threaded shank and the fork legs on P/N 404052 and from the edge of the chrome plated rod area to the fork legs on P/N 1005032 for fatigue cracks by ultrasonic method, magnetic particle method or an equivalent approved by the Chief, Aircraft Engineering Division, FAA Western Region.

(e) Replace cracked P/N 404052 rod terminal ends before further flight. Used, uncracked parts may be used as replacements in lieu of new parts but must be inspected in accordance with (d) immediately prior to installation, and thereafter at intervals not to exceed the reinspected intervals of (a) and (b). Part Number 1005032, when used to replace P/N 404052, shall be installed in accordance with Lockheed Service Bulletin 49/SB-767 for Models 49 through 749A aircraft and Lockheed Service Bulletin 1049/SB-2144 for Models 1049-54 through 1049H Series aircraft.

(f) Replace cracked P/N 1005032 rods before further flight with parts of the same part number. Used, uncracked parts may be used as replacements in lieu of new parts but must be inspected in accordance with (d) immediately prior to installation, and thereafter at intervals not to exceed the reinspection intervals of (a) and (b).

(g) Uncracked retract cylinder terminal rod ends may be reworked as follows to qualify for the increased inspection intervals afforded in (a) and (b):

(1) Polish the radius areas between the shank and the fork legs to remove all evidence of corrosion and machine marks.

(2) Shot peen the radius areas between the shank and the fork legs to 0.012-0.016 Almen A2 intensity using 0.019-0.028 cast steel shot.

(3) Cadmium plate the polished and shot peened areas per process specification QQ-P-416, Type II, Class B, and bake at 375°-400° F. for a minimum of three hours immediately after plating.

(4) Identify the rework by stamping "A" after the original part number.

(h) Upon request of the operator, an FAA maintenance inspector, subject to prior approval of the Chief, Aircraft Engineering Division, FAA Western Region, may adjust the repetitive inspection intervals specified in this AD to permit compliance at an established inspection period of the operator if the request contains substantiating data to justify the increase for such operator.

(Lockheed Service Bulletins 49/SB-767 and 1049/SB-2144 pertain, in part, to this subject.)

This amendment shall become effective June 12, 1964.

(Secs. 313(a), 601, 603; 72 Stat. 752, 775, 776; 49 U.S.C. 1354(a), 1421, 1423)

Issued in Washington, D.C., on June 8, 1964.

W. Lloyd Lane,
Acting Director,
Flight Standards Service.

[F.R. Doc. 64-5855; Filed, June 12, 1964; 8:46 a.m.]

Title 21—FOOD AND DRUGS

Chapter I—Food and Drug Administration, Department of Health, Education, and Welfare

SUBCHAPTER B—FOOD AND FOOD PRODUCTS

PART 120—TOLERANCES AND EXEMPTIONS FROM TOLERANCES FOR PESTICIDE CHEMICALS IN OR ON RAW AGRICULTURAL COMMODITIES

Status of Benzaldehyde Used as Bee Repellant

Under the authority provided in the Federal Food, Drug, and Cosmetic Act (secs. 408, 701, 68 Stat. 511 as amended, 52 Stat. 1055 as amended; 21 U.S.C. 346a, 371) and delegated to the Commissioner of Food and Drugs by the Secretary of Health, Education, and Welfare (21 CFR 2.90; 29 F.R. 471) the regulations in Subparts A and B of Part 120 are amended as follows:

1. The name "Pesticide Branch" is changed to read "Petitions Control Branch" in the following sections: §§ 120.1(d), 120.2(b), 120.7 (a), (b), (d), (e) and 120.8.

2. Benzaldehyde has been generally recognized as safe when used as a flavor in foods in accordance with good manufacturing practice. The Commissioner has received an inquiry regarding the status of this chemical when used as a bee repellant in the harvesting of honey. When so used, residues are generally less than an amount that would impart flavor to the honey. To clarify the status of this chemical under section 408 of the act, § 120.2(a) is amended to read:

§ 120.2 Pesticide chemicals considered safe.

(a) As a general rule, pesticide chemicals other than benzaldehyde (when used as a bee repellant in the harvesting of honey), ferrous sulfate, lime, lime-sulfur, potassium polysulfide, sodium carbonate, sodium chloride, sodium polysulfide, and sulfur are not for the purposes of section 408(a) of the act generally recognized as safe for use.

Notice and public procedure and delayed effective date are not necessary in the issuance of this order, since the amendments are solely editorial or interpretative in nature.

Effective date. This order shall be effective on the date of its publication in the Federal Register.

(Secs. 408, 701, 68 Stat. 511 as amended, 52 Stat. 1055 as amended; 21 U.S.C. 346a, 371)

Dated: June 8, 1964.

John L. Harvey,
Deputy Commissioner
of Food and Drugs.

[F.R. Doc. 64-5883; Filed, June 12, 1964; 8:48 a.m.]

PART 121—FOOD ADDITIVES

Subpart A—Definitions and Procedural and Interpretative Regulations

FURTHER EXTENSIONS OF EFFECTIVE DATE OF STATUTE FOR CERTAIN SPECIFIED FOOD ADDITIVES

As provided in the Federal Food, Drug, and Cosmetic Act (sec. 6(c), Public Law 85-929, as amended sec. 2, Public Law 87-19; 72 Stat. 1788, as amended 75 Stat. 42; 21 U.S.C., note under sec. 342) and delegated to the Commissioner of Food and Drugs by the Secretary of Health, Education, and Welfare (21 CFR 2.90; 29 F.R. 471), the food additive regulations (21 CFR 121.90, 121.91; 29 F.R. 2558) are amended as hereinafter set forth:

1. Section 121.90 *Further extensions of effective date of statute for certain specified food additives as direct additives to food* is amended in the following respects:

a. By extending the effective date of the following items listed under "Miscellaneous" from January 1, 1964, to June 30, 1964, and by deleting the requirement for a progress report: "Glycerin, polymerized, esterified * * *," and "triethanolamine."

b. By extending the effective date of all items now listed as January 1, 1964, under "Synthetic Flavoring Substances and Adjuncts" and under "Flavoring Substances and Natural Substances Used in Conjunction with Flavors" to a new effective date of June 30, 1964, and by deleting the requirement for a progress report for these items.

2. Section 121.91 *Further extensions of effective date of statute for certain specified food additives as indirect additives to food* is amended by extending the effective date of the following items from January 1, 1964, to June 30, 1964, and by deleting the requirement for a progress report:

Dibutyl diethylene glycol * * *.
Dilauryl ketone.
Di(oxyethyl)-diethylenetriamine * * *.
Ketone resin, cyclic * * *.
4,4'-Methylenedianiline.
m-Phenylenediamine.

Notice and public procedure and delayed effective date are not necessary prerequisites to the promulgation of this order, and I so find, since extensions of time, under certain conditions, for the effective date of the food additives amendment to the Federal Food, Drug, and Cosmetic Act were contemplated by Public Law 87-19 as a relief of restrictions of the food-processing industry.

Effective date. This order shall become effective on the date of signature.

(Sec. 6(c), Public Law 85-929, as amended, sec. 2, Public Law 87-19; 72 Stat. 1788, as amended 75 Stat. 42; 21 U.S.C., note under sec. 342)

Dated: June 8, 1964.

John L. Harvey,
Deputy Commissioner
of Food and Drugs.

[F.R. Doc. 64-5884; Filed, June 12, 1964; 8:48 a.m.]

PART 121—FOOD ADDITIVES

Subpart C—Food Additives Permitted in Feed and Drinking Water of Animals or for the Treatment of Food-Producing Animals

CHANGE OF SUBPART HEADING

Effective on the date of publication of this order in the Federal Register the heading for Subpart C of Part 121 is amended to read as set forth above.

(Sec. 409, 72 Stat. 1786; 21 U.S.C. 348)

Dated: June 8, 1964.

John L. Harvey,
Deputy Commissioner
of Food and Drugs.

[F.R. Doc. 64-5843; Filed, June 12, 1964; 8:45 a.m.]

PART 121—FOOD ADDITIVES

Subpart F—Food Additives Resulting From Contact With Containers or Equipment and Food Additives Otherwise Affecting Food

ETHYLENE-METHYL ACRYLATE COPOLYMER RESINS

The Commissioner of Food and Drugs, having evaluated the data submitted in a petition (FAP 1115) filed by Spencer Chemical Company, Dwight Building, Kansas City 5, Missouri, and other relevant material, has concluded that the food additive regulations should be amended to provide for the use of ethylene-methyl acrylate copolymer resins as the food-contact surface of articles intended for use in producing, manufacturing, packing, processing, preparing, treating, packaging, transporting, or holding dry and aqueous food only. Therefore, pursuant to the provisions of the Federal Food, Drug, and Cosmetic Act (sec. 409(c)(1), 72 Stat. 1786; 21 U.S.C. 348(c)(1)), and under the authority delegated to the Commissioner by the Secretary of Health, Education, and Welfare (21 CFR 2.90; 29 F.R. 471), Part 121 is amended by adding to Subpart F the following new section:

§ 121.2528 Ethylene-methyl acrylate copolymer resins.

Ethylene-methyl acrylate copolymer resins may be safely used as the food-contact surface of articles intended for use in producing, manufacturing, packing, processing, preparing, treating, packaging, transporting, or holding food only of the types identified in § 121.2526 (c), table 1, under categories I, II, VI, and

VIII, in accordance with the following prescribed conditions:

(a) Ethylene-methyl acrylate copolymer resins consist of basic resins produced by the copolymerization of ethylene and methyl acrylate, to which may have been added certain optional substances to impart desired technological properties to the resin. Subject to any limitations prescribed in this section, the optional substances may include:

(1) Substances generally recognized as safe in food and food packaging.

(2) Substances used in accordance with a prior sanction or approval.

(3) Substances permitted for use in ethylene-methyl acrylate copolymer resins by other regulations in this Subpart F subject to the provisions of such regulation.

(b) The methyl acrylate content of the ethylene-methyl acrylate copolymer resins shall not exceed 16 percent by weight of the finished resin including any optional substances added under the provisions of paragraph (a) (1), (2), and (3) of this section.

(c) The provisions of this section are not applicable to ethylene-methyl acrylate copolymer resin used in the formulation of food-packaging adhesives complying with § 121.2520.

Any person who will be adversely affected by the foregoing order may at any time within 30 days from the date of its publication in the FEDERAL REGISTER file with the Hearing Clerk, Department of Health, Education, and Welfare, Room 5440, 330 Independence Avenue SW., Washington 25, D.C., written objections thereto. Objections shall show wherein the person filing will be adversely affected by the order and specify with particularity the provisions of the order deemed objectionable and the grounds for the objections. If a hearing is requested, the objections must state the issues for the hearing. A hearing will be granted if the objections are supported by grounds legally sufficient to justify the relief sought. Objections may be accompanied by a memorandum or brief in support thereof. All documents shall be filed in quintuplicate.

Effective date. This order shall be effective on the date of its publication in the FEDERAL REGISTER.

(Sec. 409(c)(1), 72 Stat. 1786; 21 U.S.C. 348 (c)(1))

Dated: June 9, 1964.

JOHN L. HARVEY,
Deputy Commissioner
of Food and Drugs.

[F.R. Doc. 64-5885; Filed, June 12, 1964; 8:48 a.m.]

Title 29—LABOR

Chapter V—Wage and Hour Division, Department of Labor

SUBCHAPTER A—REGULATIONS

PART 657—TOBACCO INDUSTRY IN PUERTO RICO

Wage Rates

Pursuant to sections 5, 6, and 8 of the Fair Labor Standards Act of 1938 (29 U.S.C. 205, 206, and 208), the Secretary of Labor by Administrative Order No. 581 (29 F.R. 6092) appointed and convened Review Committee 8 and referred to it and duly noticed a hearing on the question of the minimum rate or rates of wages to be paid under paragraph (C) of Proviso (1) of subsection 6(c) of the Act in lieu of those provided under paragraph (B) of Proviso (1) to employees in the tobacco industry in Puerto Rico as that industry is defined in 29 CFR 657.1.

Subsequent to an investigation and a hearing conducted pursuant to the notice, the committee filed with the Administrator a report containing its findings and recommendations with respect to the matters referred to it.

Accordingly, as authorized and required by sections 6 and 8 of the Fair Labor Standards Act of 1938, Reorganization Plan No. 6 of 1950 (3 CFR 1949–53 Comp., p. 1004), and General Order No. 45–A of the Secretary of Labor (15 F.R. 3290), the recommendations of the committee are hereby published in this order amending the introductory paragraph of § 657.2 and § 657.2(a) (1), (2)(i), (3)(i), and (4)(i), and by establishing a new paragraph (a)(5), effective June 24, 1964, to read as follows:

§ 657.2 Wage rates.

The tobacco industry in Puerto Rico is divided into six classifications. Wages at rates not less than those prescribed in this section shall be paid under subsection 6(c) of the Fair Labor Standards Act of 1938 by every employer to each of his employees in each of the classifications in the tobacco industry in Puerto Rico who in any workweek is engaged in commerce or in the production of goods for commerce or is employed in an enterprise engaged in commerce or in the production of goods for commerce as those terms are defined in section 3 of the Act.

(a) *Previously covered classifications.*

* * *

(1) *Filler tobacco processing classification.* (i) The minimum wage for this classification is 48 cents an hour.

(ii) This classification is defined as the processing of all filler tobaccos including, but without limitation, the grading, fermenting, packing, storing, drying and handling of filler tobaccos prior to their use in the manufacture of cigars or other finished products, and including all activities performed as a necessary incident to such processing in the place of employment where such processing is carried on: *Provided, however,* That this classification shall not include such activities when they are performed as part of an integrated machine processing operation, and provided further, that this classification shall not include the shredding, chopping, threshing, stemming of such tobaccos by machine and operations immediately incidental thereto, or stemming such tobaccos by hand.

(2) *Wrapper type tobacco processing classification.* (i) The minimum wage for this classification is 88 cents an hour.

* * * * *

(3) *Machine threshing, other operations classifications.* (i) The minimum wage for this classification is 85 cents an hour.

* * * * *

(4) *General classification.* (i) The minimum wage for this classification is $1.06 an hour.

* * * * *

(5) *Filler hand stemming classification.* (i) The minimum wage for this classification is 50 cents an hour.

(ii) This classification is defined as the removing of the stem from the leaf by hand on all filler tobaccos.

(Sec. 8, 52 Stat. 1064; 29 U.S.C. 208)

Signed at Washington, D.C., this 10th day of June 1964.

CLARENCE T. LUNDQUIST,
Administrator.

[F.R. Doc. 64-5903; Filed, June 12, 1964; 8:49 a.m.]

Title 45—PUBLIC WELFARE

Chapter I—Office of Education, Department of Health, Education, and Welfare

PART 142—LOANS TO PRIVATE NONPROFIT SCHOOLS FOR ACQUISITION OF EQUIPMENT FOR STRENGTHENING INSTRUCTION IN SCIENCE, MATHEMATICS, AND MODERN FOREIGN LANGUAGES

Part 142 of Title 45 of the Code of Federal Regulations, dealing with regulations for the administration of section 305 of Title III of the National Defense Education Act of 1958, as amended, 20 U.S.C. 445, is revised to read as follows:

Subpart A—Scope of Section 305

Sec.
142.1 Purpose of loan program.

Subpart B—Definitions

142.2 Definitions.

Subpart C—Application

142.3 Application for loan.

Subpart D—Loan Procedures

142.4 Review of application.
142.5 Action on approved applications.
142.6 Loan conditions.
142.7 Interest.
142.8 Repayment.
142.9 Reports and records.

AUTHORITY: The provisions of this Part 142 issued under secs. 305, 72 Stat. 1590, and 1001, 72 Stat. 1602; 20 U.S.C. 445, 581.

Subpart A—Scope of Section 305

§ 142.1 Purpose of loan program.

The Federal Government makes loan funds available under the provisions of section 305 of the Act to eligible private nonprofit elementary and secondary schools for the acquisition of equipment suitable for use in providing education in science, mathematics, and modern foreign languages, and for minor remodeling of laboratory or other space used for such equipment.

Subpart B—Definitions

§ 142.2 Definitions.

As used in this part:

(a) "Act" means the National Defense

Education Act of 1958 (72 Stat. 1580), as amended, 20 U.S.C. Ch. 17.

(b) "Application" means a request to borrow funds from the United States under section 305(b) of the Act, submitted to the Commissioner in such form as he may require.

(c) "Audiovisual library" means a facility operated by a school or a group of schools under a school system for the collection, custody, cataloging, maintenance, and distribution of audiovisual materials for use in science, mathematics, or modern foreign language education in elementary or secondary schools.

(d) "Commissioner" means the United States Commissioner of Education, Department of Health, Education, and Welfare.

(e) "Department" means the Department of Health, Education, and Welfare.

(f) "Elementary school" means a school which provides elementary education, as determined under State law.

(g) "Equipment" means laboratory and other special equipment as defined in paragraph (h) of this section and materials as defined in paragraph (i) of this section.

(h) "Laboratory and other special equipment" means (1) fixed or movable articles, which are particularly appropriate for use in providing science, mathematics, or modern foreign language education in an elementary or secondary school, and which are to be used either by teachers in connection with teaching or by students in learning in such courses; (2) audiovisual equipment, such as motion picture, slide, filmstrip, overhead, and micro projectors, recording equipment, and television receivers, to be used, either by teachers in connection with teaching or by students in learning, primarily in providing education in science, mathematics, or modern foreign languages in an elementary or secondary school; (3) "materials" as defined in paragraph (i) of this section, and devices (other than for duplication or printing, such as mimeograph machines, ditto machines, and offset printing machines and standard keyboard typewriters) to be used primarily for preparation of science, mathematics, or modern foreign language audiovisual materials; (4) storage equipment to be used solely for the care and protection of the foregoing items when used in laboratories or classrooms for science, mathematics, or modern foreign language education; (5) test grading equipment to be used primarily in providing education in science, mathematics, or modern foreign languages in an elementary or secondary school; and (6) specialized equipment for audiovisual libraries serving elementary or secondary schools when such equipment is to be used primarily in providing science, mathematics, or modern foreign language education. (The term does not include such items as general-purpose furniture, radio, or television broadcasting apparatus, intercommunication systems, or items for the maintenance and repair of equipment except equipment provided for in subparagraph (6) of this paragraph.)

(i) "Materials" means those items which with reasonable care and use may be expected to last for more than one year and are suitable for and are to be used in providing education in science, mathematics, or modern foreign languages in an elementary or secondary school. The term includes such items as tapes and discs; slides and transparencies; films and filmstrips; books, pamphlets, and periodicals for reference use; and other printed and published materials such as maps and charts. The term does not include such items as textbooks (as defined in paragraph (t) of this section) or chemicals and other supplies which are consumed in use.

(j) "Mathematics" means the study of shape, arrangement, and number through units of courses normally required of pupils in elementary grades, or for high school graduation, or for admission to post high school institutions, and through elective courses.

(k) "Minor remodeling" means those minor alterations in a previously completed building in space used or to be used as a laboratory or classroom for science, mathematics, or modern foreign language education, which are necessary to make effective use of equipment used in providing education in science, mathematics, or modern foreign languages. The term also includes those minor alterations in a previously completed building which are necessary to make effective use of the items referred to in subparagraphs (5) and (6) of paragraph (h) of this section. The term may also include the extension of utility lines, such as for water and electricity, from points beyond the confines of the space in which the minor remodeling is undertaken but within the confines of such previously completed building, to the extent attributable to make effective use of equipment used in providing education in science, mathematics, or modern foreign languages. The term does not include building construction, structural alterations to building, building maintenance, or building repairs. Minor remodeling may be done in a building owned by or under lease to the applying school. If the building is leased, the leasehold interest shall be sufficient in the light of the cost of the remodeling to be accomplished with loan funds.

(l) "Modern foreign language" means a language, other than English, which is in current use as a common medium of communication by some substantial segment of the world population. (Latin is not a modern foreign language.)

(m) "Nonprofit," as applied to a school, means a school, owned and operated by one or more nonprofit corporations or associations no part of the net earnings of which inures, or may lawfully inure, to the benefit of any private shareholder or individual.

(n) "Private," as applied to a school, means a school which is established by an agency other than a State or a political subdivision or any combination of either or both, and which is supported in whole or in part by other than public funds and is administered and controlled by other than publicly elected or appointed officials.

(o) "Project" means a proposal by a school, as detailed in a loan application, to strengthen instruction in science, mathematics, or modern foreign languages, through the acquisition of laboratory or other special equipment or minor remodeling.

(p) "School" means a division of instructional organization consisting of a group of pupils comprised of one or more grade groups, organized on a class basis as one unit with one or more teachers to give instruction of a defined type, and housed in a school plant of one or more buildings. More than one school may be housed in one school plant as is the case when the elementary and secondary schools are housed in the same school plant.

(q) "Science" includes the physical and biological sciences, but not the social sciences.

(r) "Secondary school" means a school which provides secondary education, as determined under State law, except that the term does not include any education provided beyond grade 12.

(s) "State" means a State of the Union, Puerto Rico, the District of Columbia, the Canal Zone, Guam, American Samoa, or the Virgin Islands.

(t) "Textbook" means a book, workbook or manual, a copy of which is expected to be available for the individual use of each pupil.

Subpart C—Application

§ 142.3 Application for loan.

(a) *Filing application.* A private nonprofit school, or its governing authority, desiring to borrow funds shall file an application for that purpose with the Commissioner.

(b) *Content of application.* Such application shall include:

(1) An appropriate identification of the applicant school;

(2) Satisfactory evidence of the applicant's eligibility as a private nonprofit elementary or secondary school;

(3) Statements of financial condition and information concerning credit of the applicant and of any proposed guarantor;

(4) A request for a loan in a definite amount;

(5) A proposed plan of repayments of principal, with interest, within 10 years of the date of the loan;

(6) An itemized list of the equipment, including materials, which is proposed to be acquired with the loan funds and the estimated cost thereof, the list to be organized by subject area and grade level at which the equipment is to be used;

(7) If funds are requested for minor remodeling, a specification of the work to be done, the cost thereof, and the necessity for the remodeling in order to make effective use of equipment;

(8) Certification that the equipment is to be used primarily for providing education in science, mathematics, or modern foreign languages, except that in the case of storage equipment it will be used solely for the care and protection of equipment, including materials for science, mathematics, or modern foreign language education, and a certification that the minor remodeling, if any, is to

be performed to make effective use of equipment in science, mathematics, or modern foreign language education;

(9) A description showing the direct relationship of the proposed expenditures to the overall design for enriching the planned educational program and the achievement of desired curriculum goals in the particular subject areas; and

(10) Such additional information as the Commissioner may require.

(c) *Authorization for application.* The application shall be signed by an authorized representative of the school, and shall contain satisfactory evidence of—

(1) The authority to make the loan application;

(2) The designation of the person signing the application as a representative of the school authorized to negotiate for the loan;

(3) The legal identification of the corporation, association or other entity that will be the maker of the note; and

(4) A designation, by title, of the officer, or officers, empowered to execute the note on behalf of such entity.

Subpart D—Loan Procedures

§ 142.4 Review of application.

Action with respect to approving a loan application will be taken only after a review of information contained in the application and any other pertinent information which the Commissioner may possess.

§ 142.5 Action on approved applications.

(a) *Execution of note.* After the Commissioner approves an application for a loan, he will so notify the applicant. Upon receipt of a request for funds, the Commissioner will require the execution of a promissory note, which will include a schedule of payments of principal, with interest accruing on the unpaid principal of the loan to the dates of such payments.

(b) *Payment to school.* Upon receipt of a duly executed note, the Commissioner will cause the loan funds to be paid to the applicant.

(c) *Rescission of loan approval.* If the applicant does not request the loan funds within a reasonable time, the Commissioner may rescind the approval of the loan application.

§ 142.6 Loan conditions.

(a) *Limitation on amount.* Each loan will be limited to the amount which may reasonably be expected to be expended without undue delay for the acquisition of equipment or for minor remodeling.

(b) *Assurance of repayment.* All loans will be made on the basis of such security or evidence of financial responsibility as will reasonably assure repayment.

(c) *Use of loan funds.* All loans will be subject to the condition that the funds borrowed will be used only for the acquisition of equipment, or for the performance of minor remodeling, substantially similar to the project described in the approved application.

(d) *Unused funds.* Loan funds that are not used within a reasonable time shall immediately become due and payable, with interest accrued thereon. If an applicant fails to file a completion report as required by § 142.9 within a reasonable time, the loan funds may be deemed not to have been used. This paragraph applies only if the total amount not used equals or exceeds two percent of the amount lent or $200, whichever is smaller.

(e) *Misused funds.* Such of the loan funds amounting to or exceeding two percent of the amount lent or $200, whichever is smaller, as are used in a manner that does not comply with the conditions set forth in paragraph (c) of this section may be immediately declared due and payable, with interest accrued thereon. However, if any of the loan funds are used for purposes other than those provided for in § 142.1, the entire unpaid balance of the loan shall immediately become due and payable, with interest accrued thereon.

(f) *Disposal and diversion of equipment acquired.* If during the period of the loan the applicant diverts equipment to an unauthorized purpose, or disposes of such equipment, the unpaid balance of the loan shall, at the option of the Commissioner, become immediately due and payable, with interest accrued thereon. Any diversion or disposal of equipment shall immediately be reported to the Commissioner.

(g) *Time of acquisition.* Loan funds shall not be used for the acquisition of equipment, including minor remodeling, for which firm commitments have been made prior to the approval of the application.

(h) *Equipment from a Communist country.* Annual appropriation acts for the Department of Health, Education, and Welfare, such as the Department of Health, Education, and Welfare Appropriation Act, 1963 (76 Stat. 361, 367) and 1964 (77 Stat. 224, 231), have provided that no part of the funds appropriated for "Defense Educational Activities" shall be available for the purchase of science, mathematics, or modern language teaching equipment, or equipment suitable for use for teaching in such fields of education, which can be identified as originating in or having been exported from a Communist country, unless such equipment is unavailable from any other source. Accordingly, such a condition would apply to all loans made under section 305 of the Act. A violation of such a condition would constitute a misuse of funds which will cause them to become immediately due and payable, with interest accrued thereon. Inquiry should be made of the Commissioner if the applicant has any question whether a specific proposed use of loan funds might violate such a condition.

§ 142.7 Interest.

(a) *Determination of interest rate.* Loans will bear interest at the rate arrived at by adding one-quarter of one per centum per annum to the rate which the Secretary of the Treasury determines to be equal to the current average yield on all outstanding marketable obligations of the United States as of the last day of the month preceding the date the application for the loan is approved and by adjusting the result so obtained to the nearest one-eighth of one per centum.

(b) *Effective interest rate.* The interest rate in effect at the time a loan is approved will remain in effect for the life of the loan.

(c) *Date of loan.* The date of the U.S. Treasury check issued to the applicant covering the loan to it will be the date of the loan and the date from which the interest accrues.

§ 142.8 Repayment.

(a) *Schedule of repayments.* Repayments of principal with accrued interest shall be made on such dates as may be agreed upon by the Commissioner and the applicant.

(b) *Date of maturity.* A loan may be made for any period of time except that the date of maturity shall be not more than ten years after the date on which the loan is made.

(c) *Prepayment.* Loans may be prepaid in full or in part at any time, with accrued interest to the date of payment, without penalty for prepayment.

§ 142.9 Reports and records.

(a) *Reports.* Each applicant receiving a loan shall furnish a completion report upon completing the approved project, and shall furnish such progress or other reports as the Commissioner may from time to time require regarding the use of loan funds.

(b) *Records.* Each applicant receiving a loan shall keep the loan in a separate bank account or maintain a separate accounting of such funds sufficient to readily identify all transactions with the loan funds. Each such applicant shall also maintain intact all records supporting the use of loan funds for three years after receipt of such funds, or until the loan has been repaid in full, whichever is later. Such records shall be made available to fiscal representatives of the Government for audit purposes.

[SEAL] FRANCIS KEPPEL,
U.S. Commissioner of Education.

Approved: June 8, 1964.

ANTHONY J. CELEBREZZE,
Secretary of Health,
Education, and Welfare.

[F.R. Doc. 64-5846; Filed; June 12, 1964; 8:45 a.m.]

PART 160—TRAINING PROGRAM UNDER THE MANPOWER DEVELOPMENT AND TRAINING ACT OF 1962

Part 160 of Title 45 of the Code of Federal Regulations, dealing with the rules and regulations for the administration of Part B of Title II of the Manpower Development and Training Act of 1962, 76 Stat. 30, as amended, 42 U.S.C. Chap. 30, is revised to reflect the amendments made to the Act by Public Law 88-214, 77 Stat. 422. As so revised Part 160 reads as follows:

Sec.
160.1 Definitions.
160.2 Summary of program.
160.3 Services and facilities for the provision of training.

Sec.
160.4 Approval of projects.
160.5 Payment to State Agency.
160.6 Allowable costs.
160.7 Payment procedures.
160.8 Effect of payments.
160.9 Fiscal procedures.
160.10 Title to equipment and teaching aids.
160.11 Separate records.
160.12 Evaluation.
160.13 Records retention.
160.14 Fees and charges.

AUTHORITY: The provisions of this Part 160 issued under § 232, 76 Stat. 30.

§ 160.1 Definitions.

(a) "Act" means the Manpower Development and Training Act of 1962, 76 Stat. 23, as amended; 42 U.S.C. Chap. 30.

(b) "Agreement" means the written agreement for training, other than on-the-job training, entered into pursuant to section 231 of the Act between a State and the Commissioner acting for the Secretary.

(c) "Commissioner" means the U.S. Commissioner of Education or his duly authorized representative.

(d) "Public", as applied to any training agency or institution, means an agency or institution under public supervision and control.

(e) "Referred person" means an unemployed or other person referred to a State Agency for training under the Act and the Agreement.

(f) "Secretary" means the Secretary of the U.S. Department of Health, Education, and Welfare.

(g) "State" means any one of the fifty States, the District of Columbia, Puerto Rico, the Virgin Islands, or Guam.

(h) "State advisory committee" means the State-level committee provided for under and authorized by the State Agency in connection with its functions under the Agreement.

(i) "State Agency" means the authorized State vocational education agency designated in the Agreement.

(j) "Training" means a planned and systematic sequence of instruction under competent supervision designed to impart predetermined skill, knowledge, or abilities with respect to designated occupational objectives and may include, to the extent necessary, instruction in basic education which is given in relation to the occupational objectives sought.

(k) "Training project" means a program or course, including a special youth project, for the training of a given number of referred individuals.

(l) "Unemployed", as used in connection with a referred person, means an individual whose status is so determined and certified by the Secretary of the U.S. Department of Labor or his designated representative.

(m) "Basic education" means elementary level education, usually in the general areas of reading, writing, language skills, and arithmetic, given in order to enable the trainee to pursue a program of occupational training.

(n) "Special youth project" means a project providing guidance, counseling, testing, basic education, basic work skills, social adjustment, occupational training, or other instruction or special services to meet the needs of youths sixteen years of age or older who because of inadequate educational background and work preparation are unable to qualify for and obtain employment without such training or schooling.

§ 160.2 Summary of program.

(a) *State participation in the Manpower Development and Training Program.* Each State which has entered into an Agreement has agreed to provide the training needed to equip both unemployed and other persons referred for training under the Act for the purposes that are specified in the referrals.

(b) *Conduct of training projects.* Under the Agreement the State Agency shall provide the necessary training through public educational agencies or institutions or through arrangements with private educational or training institutions; provided, however, it is determined that such private educational or training institutions can provide substantially equivalent training with reduced Federal expenditures. Federal expenditures for training projects will be estimated on the basis of cost per referred trainee.

(c) *State Agency's responsibility for training.* Notwithstanding any arrangements it may make for the conduct of training projects, the State Agency is responsible for taking such steps as are necessary to assure that training projects are expeditiously formulated for the training of referred persons and that the quality and adequacy of the training provided under such projects are consistently maintained. In any case in which it appears that the State Agency will be unable to arrange for the training of referred persons within the State, the Agency shall promptly notify the Commissioner to that effect. In that event, or in the case of training under subsection (b) or (i) of section 202 of the Act, the Commissioner, acting for the Secretary, may make arrangements for the training through other appropriate educational agencies.

§ 160.3 Services and facilities for the provision of training.

(a) *Adequacy.* The services and facilities of any public or private educational agency or institution shall be deemed adequate for the purpose of providing training under the Agreement only upon a finding by the State Agency that such agency or institution:

(1) Is generally regarded as offering quality training as reflected by such factors as its placement record and accreditation status;

(2) Will provide instructional staff for such training that meets or exceeds the State's standards of training, education, and experience for teaching similar courses in such occupations and related information;

(3) Will provide a course of instruction based on the recognized needs of the individuals who are to receive training and which, except for the basic education aspects, will provide the skills and related information (including appropriate instruction in health and safety practices) requisite for employment in the occupation or occupations for which training is to be provided;

(4) Has developed suitable standards which set forth the level of competency that will be required for the successful completion of the training project;

(5) Will have the facilities necessary for the training which is to be provided, including, but not limited to, space, tools, machines, supplies, and teaching aids;

(6) Will establish and maintain appropriate standards relating to health and safety in the conduct of the training; and

(7) Is financially sound and capable of fulfilling its commitments for training.

(b) *Nondiscrimination.* Training under the Act shall be given without distinction because of race, creed, color, or national origin.

§ 160.4 Approval of projects.

(a) *In general.* (1) Prior to the commitment of any funds for any training project, a proposal for the conduct of such project and a project budget prepared on the basis of the estimated costs of the training involved must be approved by the State Agency and the Commissioner.

(2) Project proposals and budgets will be approved by the Commissioner only if he is satisfied that the State Agency has taken all the steps necessary pursuant to the Agreement to assure high quality training and efficient utilization of resources.

(b) *Budgeting for training projects.* A budget (including directly attributable local supervisory costs as a separate item) shall be prepared for each proposed project for training and shall be reviewed by the State Agency in conjunction with its review of each proposed project.

(c) *Budgets for State administrative and supervisory costs.* An over-all budget estimate covering the cost of State administration and of supervision of the training program within the State under the Agreement shall be separately prepared and submitted to the Commissioner for approval. If the State Agency intends to expend any funds in connection with its utilization of the State advisory committee, such expenditure shall be separately identified and, to the extent permitted under the Agreement, included in the budget provided for under this subparagraph.

(b) *Maximum Federal commitment.* In order to assure that the Federal funds committed with respect to all approved training projects within any State and the State Agency's administration and supervision of the program do not exceed the total funds available for those purposes, each budget shall represent the maximum amount the Commissioner shall be obligated to pay the State Agency for such administration, supervision, or training. The maximum Federal financial commitment with respect to each budget may, with the approval of the State Agency and the Commissioner, be revised from time to time as reductions or increases in anticipated expenditures may warrant.

§ 160.5 Payment to State Agency.

(a) *In general.* Within budget estimates therefor which have been approved by the State Agency and the Commissioner, the State Agency will be paid the applicable percentage of the allowable costs incurred in connection with training projects.

(b) *Determination of Federal share of allowable costs—training projects.* Subject to the maximum Federal commitment under § 160.4(d), the Federal share of all allowable costs incurred in connection with training provided under each project shall be (1) prior to July 1, 1965, 100 percent of the allowable costs which are attributable to the training of unemployed referred persons, (2) thereafter, 66⅔ percent of the allowable costs which are so attributable, and (3) during any fiscal year, 50 percent of the allowable costs which are attributable to the training of other referred persons. The approval of any project shall be subject to the availability of such State and/or local matching funds as may be required.

(c) *Determination of Federal share of allowable costs—State administration and supervision.* Subject to the maximum Federal commitment under § 160.4 (d), the Federal share of allowable costs incurred in connection with the State Agency's administration and supervision of the program (including expenses of the State advisory committee) shall be (1) prior to July 1, 1965, 100 percent of the total allowable costs of such administration and supervision, and (2) thereafter 66⅔ percent of such allowable costs.

§ 160.6 Allowable costs.

(a) *State administration of program.* To the extent that the items of cost are attributable to the carrying out of the responsibilities of the State Agency under the Agreement, the allowable costs of the State Agency in its administration and supervision of the program of training may include such categories of expenses as the following: (1) Salaries (including employer's contributions to retirement, workmen's compensation, and other welfare funds maintained for one or more general classes of employees of the State Agency) of the staff, both clerical and professional; (2) equipment necessary for continuous supervision of the training projects conducted under the Agreement to insure the quality and adequacy of the training provided; (3) communications; (4) supplies, printing, and printed material; (5) office space as provided for in paragraph (c) of this section; (6) necessary transportation and per diem for the State advisory committee to the extent permitted under the Agreement; (7) travel of staff; (8) out-of-area travel of local supervisors when undertaken at the request of the State Agency; (9) short intensive programs for orientation and development of instructional staff; (10) the necessary development of instructional materials; (11) special assistance to large cities, metropolitan areas, and large intermediate areas of sparse population for the purpose of developing and extending training projects where approved by the Commissioner, such assistance to include but not be limited to the subparagraphs (1) through (7) of this paragraph; and (12) transportation and storage of supplies and equipment obtained from Federal excess or surplus property, the National Industrial Reserve, or completed manpower projects within the State or from other jurisdictions.

(b) *Costs of training projects.* The allowable costs of the State Agency in the conduct of each training project either directly or by arrangement with public or private educational agencies or institutions may include, to the extent related to the conduct of an approved project and included in an approved project budget: (1) Salaries (including employer's contributions to retirement, workmen's compensation, and other welfare funds maintained for one or more general classes of employees): (i) Of local vocational educational supervisory and supporting clerical staff and (ii) of instructional staff; (2) teaching aids, training manuals and materials, supplies, and equipment including the purchase, transportation, rental, and/or maintenance of equipment; (3) rental, when publicly owned space is not available, utilities and custodial services for shop, classroom, and laboratory space; (4) in the case of arrangements for the conduct of training projects with private educational agencies or institution, in lieu of subparagraphs (1)(ii) through (3) of this paragraph, reasonable tuition and other charges, normally made by the facility for similar training; (5) transportation within the geographic area of local supervisors in carrying out supervisory responsibilities in connection with approved training projects; (6) minor remodeling of public buildings, if necessary, to make existing space suitable for classroom, shop, or laboratory purposes for a training project or projects; (7) accident or liability insurance to the extent it is the policy of the school district to provide such insurance in similar programs; (8) transportation of trainees within the attendance area of the training project where such transportation is necessary under the circumstances to the attendance of the trainees; and (9) audits of projects performed under § 160.9(c).

(c) *Office space.* Allowable costs may include expenditures for office space (including the cost of utilities and janitorial services) in privately or publicly owned buildings if: (1) The expenditures for the space are necessary, reasonable, and properly related to the efficient administration of the program; (2) the State Agency will receive the benefits of the expenditures during the period of occupancy; (3) the amounts paid by the State Agency are not in excess of comparable rental in a particular locality; and (4) the expenditures represent an actual cost to the State Agency.

(d) *Proration of costs.* Only costs which are solely attributable to the carrying out of the provisions of the Agreement may be considered to be allowable costs. Budgets which include items of expenditure only part of which are attributable to carrying out the provisions of the Agreement must indicate the basis on which the portion of the total program costs is determined.

§ 160.7 Payment procedures.

(a) States which have entered into the Agreement shall be advanced from time to time such amounts (within the limits of available funds) as determined by the Commissioner on the basis of estimates of funds needed in carrying out the Agreement and such other information as he may have requested or have available.

(b) Upon notice to the State Agency that the Commissioner has determined that unused advances to a State Agency are in excess of its needs for carrying out the Agreement for a reasonable period, such excess will be returned to the Commissioner.

§ 160.8 Effect of payments.

Neither the approval of any project or administrative budget nor any advance or other payment made to the State Agency pursuant thereto shall be deemed to waive the right or duty of the Commissioner to withhold funds by reason of the failure of the State Agency to observe, before or after such administrative action, any Federal requirement.

§ 160.9 Fiscal procedures.

(a) The State Agency may make payments in advance or by way of reimbursement to agencies or institutions conducting training under the Agreement. Except for tuition payments to private institutions as provided in an approved training project such payments shall be supported by statements of proposed expenditures or by statements of expenditures on forms provided by the Commissioner.

(b) The advance of funds to an institution or agency will not be deemed an expenditure of such funds for purpose of the State's accountability for the expenditure of Federal funds under the Agreement.

(c) The State Agency will require each training institution or agency to keep adequate records by budget classification of expenditures made for each training project. Where training is procured from a public or private agency or institution on a reimbursable basis, prior to final settlement for a training project, the State Agency will satisfy itself through an audit by an appropriate State audit agency or staff or independent certified public accountant, of the correctness of amounts claimed by the training agency or institution. Such audits shall be conducted in accordance with standards approved by the Commissioner.

(d)(1) When the unit cost is $50.00 or more, the State Agency shall maintain an up-to-date inventory of (i) all equipment and teaching aids purchased as a part of a training project approved under the Act and (ii) all equipment purchased for use in State administration and supervision of training. A separate inventory must be maintained for subdivisions (i) and (ii) of this subparagraph.

(2) All equipment inventoried under subparagraph (1)(i) of this paragraph

must be clearly marked to enable its easy identification as having been purchased with funds provided under the Act.

§ 160.10 Title to equipment and teaching aids.

(a) Upon the termination of the Federal statutory authorization for Federal financial participation for the purposes of Part B of the Act, any equipment and teaching aids purchased by a State or local education agency with funds to carry out the provisions of the Agreement shall become the property of the State.

(b) Excess Federal personal property is available, on a loan basis, through the State Agency for purposes of training projects. The right of possession only is granted to the State Agency; the title to such property remains in the United States. The use of such property by a State Agency is subject to the following conditions: (1) The State Agency shall maintain separate records of all excess Federal personal property received in such form and detail as will permit the location and identification of such property at any time; (2) the State Agency shall be responsible, as a bailee for mutual benefit, for such property from the time it is released to the State Agency or to the transportation agent; and (3) in the event of any loss or damage to any of such property, the State Agency shall file such claim and/or institute and prosecute to conclusion such proceedings as may be necessary to recover, for the account of the United States, the fair value of any such property lost or damaged.

§ 160.11 Separate records.

The State Agency shall maintain adequate records showing separately its activities under the Agreement for (a) State administration and supervision, and (b) training. Such records will indicate these activities as separate and distinct from other activities of the State Agency. The State Agency also will include a provision in its arrangements for training with each public and private educational agency or institution for the maintenance of records showing its training activities under the Act as separate and distinct from other activities.

§ 160.12 Evaluation.

The State Agency shall make provision for periodic reviews and evaluations of the training provided under the Agreement. Such evaluations shall include State Agency's recommendations for improvement and the need for continuing such training. Reports containing such reviews and evaluations shall be submitted by the State Agency to the Commissioner at such times as he may request.

§ 160.13 Records retention.

(a) The State Agency shall provide for keeping accessible and intact all records supporting claims for Federal funds or related to the accountability of a State Agency for expenditure of such funds and relating to the expenditure of its share of the costs of providing training under this Act.

(1) For three years after the close of the fiscal year in which the expenditure was made by the State Agency or any public or private educational agency or institution; or

(2) Until the State Agency is notified that such records are not needed for program administration review; or

(3) Until the State Agency is notified of the completion of the Federal fiscal audit, whichever is later.

(b) The records involved in any claim or expenditure which has been questioned shall be further maintained until necessary adjustments have been made and the adjustments have been reviewed and cleared by the Commissioner.

§ 160.14 Fees and charges.

No fees or charges are to be collected from trainees as a condition of enrollment, participation, or completion of any approved training course of instruction. However, the cost applicable to services or materials for which such fees or charges are normally made by the training agency to enrollees for similar training may be included as a separate item in the budget for each training project, to the extent found to be necessary thereto.

Dated: May 13, 1964.

[SEAL] FRANCIS KEPPEL,
U.S. Commissioner of Education.

Approved: June 8, 1964.

ANTHONY J. CELEBREZZE,
Secretary of Health,
Education, and Welfare.

[F.R. Doc. 64-5847; Filed, June 12, 1964; 8:45 a.m.]

Proposed Rule Making

FEDERAL AVIATION AGENCY

[14 CFR Part 71 [New]]

[Airspace Docket No. 64-PC-3]

FEDERAL AIRWAY SEGMENT

Proposed Revocation

In consonance with ICAO International Standards and Recommended Practices, notice is hereby given that the Federal Aviation Agency (FAA) is considering an amendment to Part 71 [New] of the Federal Aviation Regulations. This proposal relates to navigable airspace outside the United States.

Applicability of International Standards and Recommended Practices by the Air Traffic Service, FAA, in areas outside domestic airspace of the U.S. is governed by Article 12 and Annex 11 to the Convention on International Civil Aviation (ICAO), which pertains to the establishment of air navigation facilities and services necessary to promoting safe, orderly and expeditious flow of civil air traffic. Its purpose is to insure that civil flying on international air routes is carried out under uniform conditions designed to improve the safety and efficiency of air operations.

The International Standards and Recommended Practices in Annex 11 apply to those parts of the airspace under the jurisdiction of a contracting state, derived from ICAO, wherein air traffic services are provided and also whenever a contracting state accepts the responsibility of providing air traffic services over high seas or in airspace of undetermined sovereignty. A contracting state accepting such responsibility may apply the International Standards and Recommended Practices to civil aircraft in a manner consistent with that adopted for airspace under its domestic jurisdiction.

In accordance with Article 3 of the Convention on International Civil Aviation, Chicago, 1944, state aircraft are exempt from the provisions of Annex 11 and its Standards and Recommended Practices. As a contracting state, the U.S. agreed by Article 3(d) that its state aircraft will be operating in international airspace with due regard for the safety of civil aircraft.

Since this action involves in part the designation of navigable airspace outside the United States, the Administrator has consulted with the Secretary of State and the Secretary of Defense in accordance with the provisions of Executive Order 10854.

Amber Federal airway No. 11 is designated from the intersection of the south course of the Maui, Hawaii, radio range and west course of the Hilo, Hawaii, radio range to the intersection of the north course of the Maui radio range and a point 38 miles north of the Maui radio range. The Federal Aviation Agency proposes to revoke Amber 11. It is the Agency policy to replace low frequency Federal airways, wherever possible, with airways based on more modern VOR navigational facilities. The Agency, in Airspace Docket No. 64-PC-1, is proposing to designate VOR Federal airway No. 5, Hawaii, from the intersection of the Lanai, Hawaii, 118° and the Maui, Hawaii, 179° True radials; via the intersection of the Lanai 140° and the Maui 179° True radials; to the intersection of the Lanai 140° and the Upolu Point 211° True radials. Victor 5 as proposed therein would replace the segment of Amber 11 south of Maui and provide a shorter route for VOR-equipped aircraft operating between Honolulu, Hawaii, and Kona Airport on the west coast of the island of Hawaii. The latest Federal Aviation Agency peak day airway traffic survey for the segment of Amber 11, north of Maui shows no aircraft movements. Therefore, it would appear that this segment of Amber 11 is unjustified as an assignment of airspace. Adoption of this proposal would not result in the decommissioning of the low frequency navigational aids associated with this airway. Any proposals to discontinue one or more of these aids would be circularized separately and interested persons would be afforded an opportunity to comment.

Interested persons may submit such written data, views or arguments as they may desire. Communications should be submitted in triplicate to the Director, Pacific Region, Attn: Chief, Air Traffic Division, Federal Aviation Agency, P.O. Box 4009, Honolulu, Hawaii, 96812. All communications received within forty-five days after publication of this notice in the FEDERAL REGISTER will be considered before action is taken on the proposed amendment. No public hearing is contemplated at this time, but arrangements for informal conferences with Federal Aviation Agency officials may be made by contacting the Regional Air Traffic Division Chief, or the Chief, Airspace Regulations and procedures Division, Federal Aviation Agency, Washington, D.C., 20553. Any data, views or arguments presented during such conferences must also be submitted in writing in accordance with this notice in order to become part of the record for consideration. The proposal contained in this notice may be changed in the light of comments received.

The official docket will be available for examination by interested persons at the Federal Aviation Agency, Office of the General Counsel: Attention Rules Docket, 800 Independence Avenue SW., Washington, D.C. An informal docket will also be available for examination at the office of the Regional Air Traffic Division Chief.

(Sec. 307(a), 1110, 72 Stat. 749, 800; 49 U.S.C. 1348, 1510, E.O. 10854, 24 F.R. 9565)

Issued in Washington, D.C., on June 5, 1964.

H. B. HELSTROM,
Acting Chief, Airspace Regulations and Procedures Division.

[F.R. Doc. 64-5856; Filed, June 12, 1964; 8:46 a.m.]

[14 CFR Part 75 [New]]

[Airspace Docket No. 64-WA-33]

JET ROUTES

Proposed Alteration

Notice is hereby given that the Federal Aviation Agency (FAA) is considering an amendment to Part 75 [New] of the Federal Aviation Regulations, the substance of which is stated below.

Jet Route No. 78 is presently designated in part from the Tulsa, Okla., VORTAC to the Farmington, Mo., VORTAC. The FAA proposes to realign this segment via the Springfield, Mo., VORTAC. Airspace Docket No. 63-WA-74 was published in the FEDERAL REGISTER on March 28, 1964 (29 F.R. 4101), and proposes to lower the floor of all jet routes to 18,000 feet MSL. Realignment of J-78 via Springfield would situate the route in an area having better radar coverage at all altitudes, and, consequently, would improve air traffic service in this area.

Interested persons may submit such written data, views, or arguments as they may desire. Communications should be submitted in triplicate to the Chief, Airspace Regulations and Procedures Division, Federal Aviation Agency, Washington, D.C., 20553. All communications received within 30 days after publication of this notice in the FEDERAL REGISTER will be considered before action is taken on the proposed amendment. No public hearing is contemplated at this time, but arrangements for informal conferences with Federal Aviation Agency officials may be made by contacting the Chief, Airspace Regulations and Procedures Division. Any data, views, or arguments presented during such conferences must also be submitted in writing in accordance with this notice in order to become part of the record for consideration. The proposal contained in this notice may be changed in the light of comments received.

The official docket will be available for examination by interested persons at the Federal Aviation Agency, Office of the General Counsel: Attention Rules Docket, 800 Independence Avenue SW., Washington, D.C., 20553.

(Sec. 307(a), Federal Aviation Act of 1958; 72 Stat. 749; 49 U.S.C. 1348)

Issued in Washington, D.C., on June 5, 1964.

H. B. HELSTROM,
Acting Chief, Airspace Regulations and Procedures Division.

[F.R. Doc. 64-5857; Filed, June 12, 1964; 8:46 a.m.]

[14 CFR Part 91 [New]]

[Notice No. 6018; Docket No. 64-34]

RADIO FAILURE PROCEDURES IN IFR OPERATIONS

Proposed Revision

The Federal Aviation Agency is considering amending § 91.127 of the Federal Aviation Regulations to revise the established radio failure procedures in Instrument Flight Rules operations.

Interested persons may participate in the making of the proposed rule by submitting such written data, views, or arguments as they may desire. Communications should identify the regulatory docket or notice number and be submitted in duplicate to the Federal Aviation Agency, Office of the General Counsel: Attention Rules Docket, 800 Independence Avenue SW., Washington, D.C., 20553. All communications received on or before August 12, 1964, will be considered by the Administrator before taking action on the proposed rule. The proposal contained in this notice may be changed in the light of comments received. All comments submitted will be available, both before and after the closing date for comments, in the Rules Docket for examination by interested persons.

FAR § 91.127 prescribes the flight procedures to be followed by a pilot flying according to Instrument Flight Rules after a two-way radio communications failure has occurred. Paragraph (c) of the section specifies the method of determining the route and altitude to be flown after the communications failure.

There are four changes to FAR § 91.127 (c) under consideration. The first would establish the route and altitude given as part of an ATC "expect further clearance" message as the actual ATC clearance to be used by a pilot flying under Instrument Flight Rules for subsequent route and altitude after a communications failure has occurred. This would eliminate the necessity for paragraph (c) (2) (iii) of the section which now specifies the "lowest cardinal altitude or flight level at or above the MEA of the highest planned route structure * * *" as one of the alternative altitudes, the highest of which is to be maintained by a pilot flying IFR after a communications failure.

The second change would substitute the term "minimum altitude for IFR operations" for the present "minimum safe altitude" in § 91.127(c) (2) (ii). Prior to the recodification, § 60.17 of the Civil Air Regulations entitled "Minimum Safe Altitudes" included a paragraph (d) "IFR operations." The term "minimum safe altitudes" is used in the title of FAR § 91.79 under the "General Rules" portion of flight rules. That section does not expressly refer to IFR operations and may, in fact, not provide the terrain clearance required for IFR operation. FAR § 91.119, entitled "minimum altitudes for IFR operations," is the proper section governing minimum IFR altitudes. While "minimum safe altitude" as used in FAR § 91.127(c) (2) (iii) is construed to mean the minimum safe altitude for the operation being conducted, i.e. IFR, it is more appropriate to use the term "minimum altitude for IFR operation" to clearly apply the proper rule.

The third change would delete from § 91.127(c) (2) and (3) the provision for climb to the lowest cardinal altitude or flight level at or above the MEA of the highest planned route structure when a clearance has not been received and delete the provision for the climb to begin ten minutes after passing the first compulsory reporting point over which the failure prevented communications with ATC. Current ATC procedures require controllers to issue a clearance for an altitude/flight level within the highest route structure filed or the specific time or fix at which a clearance to such altitude/flight level may be expected, i.e. "expect further clearance * * *" and the proposed new wording of § 91.127(c) (2) and (3), by indicating the methods of determining the time and place to climb, render paragraphs (c) (2) (iii) and (c) (3), as presently written, unnecessary and inapplicable. Instead of requiring that the climb begin within ten minutes after passing the first compulsory reporting point, the proposed § 91.127(c) (3) would require that the climb be initiated whenever necessary to comply with IFR minimum altitude requirements, and that any subsequent climb be initiated at the time or place given in the last obtained ATC "expect further clearance * * *" message.

The fourth change would substitute the term "obtained" for "received" wherever "received" presently appears in the section in referring to a clearance or expected further clearance given by ATC to the pilot. This would reflect present ATC practice of considering a clearance or expected further clearance to have been actually accepted by the pilot only if he has affirmatively acknowledged its acceptance in a communication back to ATC. The word "obtained" is therefore used to more adequately indicate the necessity for the pilot's acknowledgment and acceptance of the clearance or expected further clearance than the term "received" which might be interpreted to include the mere transmission by ATC without any response from the pilot.

Accordingly, it is proposed to amend Subpart B of Part 91 of the Federal Aviation Regulations as hereinafter set forth.

1. Section 91.127(c) is amended to read as follows:

(c) *IFR conditions.* If the failure occurs in IFR conditions, or if paragraph (b) of this section cannot be complied with, each pilot shall continue the flight to the original destination according to the following:

(1) *Route.* (i) By the route assigned in the last air traffic control clearance obtained.

(ii) In the absence of an assigned route, by the route that air traffic control has advised may be expected in a further clearance.

(iii) In the absence of an assigned route or a route that air traffic control has advised may be expected in a further clearance, by the route filed in the flight plan.

(2) *Altitude.* At whichever of the following altitudes or flight level is the highest:

(i) At the altitude or flight level assigned in the last air traffic control clearance obtained.

(ii) At the minimum altitude for IFR operations;

(iii) At the altitude or flight level to which air traffic control has advised may be expected in a further clearance.

(3) *Climb.* When climb to comply with subparagraph (2) of this paragraph is necessary, the following applies:

(i) Climb to the assigned altitude or flight level in accordance with the last air traffic control clearance obtained;

(ii) Climb to the minimum altitude for IFR operations at the time or place necessary to comply with that minimum;

(iii) When later climb to a higher altitude or flight level is required, initiate climb at the time or place where air traffic control has specified that a clearance to a higher altitude or flight level may be expected.

(4) If holding instructions have been obtained, leave the holding fix at the expected further clearance time obtained, or, if an expected approach clearance time has been obtained, leave the holding fix so as to arrive over the radio facility to be used for the approach at the destination as close as possible to the expected approach clearance time.

(5) Begin descent from the en route altitude or flight level at the radio facility to be used for the approach at the destination at the latest of the following times:

(i) The expected approach clearance time (if obtained).

(ii) The estimated time of arrival shown on the flight plan, as amended with ATC.

(iii) The actual time of arrival over the facility.

(Sec. 307, Federal Aviation Act of 1958; 72 Stat. 749; 49 U.S.C. 1348)

Issued in Washington, D.C., on June 5, 1964.

CLIFFORD P. BURTON,
Acting Director, Air Traffic Service.

[F.R. Doc. 64-5858; Filed, June 12, 1964; 8:46 a.m.]

[14 CFR Part 507]

[Reg. Docket No. 6015]

AIRWORTHINESS DIRECTIVES

de Havilland Model 114 Heron Aircraft

The Federal Aviation Agency has under consideration a proposal to amend Part 507 of the Regulations of the Administrator to include an airworthiness directive for de Havilland Model 114

Heron aircraft. There has been an instance of cracking of an eye end in the elevator trim tab control system. To correct this condition, this AD requires inspection of the elevator trim tab connecting rod assemblies and replacement of any parts found cracked.

Interested persons are invited to participate in the making of the proposed rule by submitting such written data, views, or arguments as they may desire. Communications should identify the regulatory docket number and be submitted in duplicate to the Federal Aviation Agency, Office of the General Counsel, Attention: Rules Docket, 800 Independence Avenue SW., Washington, D.C., 20553. All communications received on or before July 13, 1964, will be considered by the Administrator before taking action upon the proposed rule. The proposals contained in this notice may be changed in the light of comments received. All comments will be available, both before and after the closing date for comments, in the Rules Docket for examination by interested persons.

This amendment is proposed under the authority of sections 313(a), 601 and 603 of the Federal Aviation Act of 1958 (72 Stat. 752, 775, 776; 49 U.S.C. 1354(a), 1421, 1423).

In consideration of the foregoing, it is proposed to amend § 507.10(a) of Part 507 (14 CFR Part 507), by adding the following airworthiness directive:

DE HAVILLAND. Applies to all Model 114 Heron aircraft.

Compliance required within 150 hours' time in service after the effective date of this AD.

As a result of cracking of eye ends used in the rudder and elevator trim tab connecting rod assemblies, accomplish the following unless already accomplished:

(a) Remove eye end, P/N's CM2A and CM2B, and make the crack test specified in T.N.S. Heron (114) No. CF10 issued February 24, 1964.

(b) Replace cracked parts before further flight.

(Hawker Siddeley Aviation, de Havilland Division T.N.S. Heron (114) No. CF10 covers this same subject.)

Issued in Washington, D.C., on June 8, 1964.

W. LLOYD LANE,
Acting Director,
Flight Standards Service.

[F.R. Doc. 64-5859; Filed, June 12, 1964; 8:46 a.m.]

[14 CFR Part 507]

[Reg. Docket No. 6016]

AIRWORTHINESS DIRECTIVES

Boeing Models 707 and 720 Series Aircraft

The Federal Aviation Agency has under consideration a proposal to amend Part 507 of the Regulations of the Administrator to include an airworthiness directive for Boeing Models 707 and 720 Series aircraft. Several instances of fin-body terminal attachment bolt failures have occurred. To correct this condition, this AD requires inspection and modification of the fin-body terminal attachment bolts.

Interested persons are invited to participate in the making of the proposed rule by submitting such written data, views, or arguments as they may desire. Communications should identify the regulatory docket number and be submitted in duplicate to the Federal Aviation Agency, Office of the General Counsel, Attention: Rules Docket, 800 Independence Avenue SW., Washington, D.C., 20553. All communications received on or before July 13, 1964, will be considered by the Administrator before taking action upon the proposed rule. The proposals contained in this notice may be changed in the light of comments received. All comments will be available, both before and after the closing date for comments in the Rules Docket for examination by interested persons.

This amendment is proposed under the authority of sections 313(a), 601 and 603 of the Federal Aviation Act of 1958 (72 Stat. 752, 775, 776; 49 U.S.C. 1354(a), 1421, 1423).

In consideration of the foregoing, it is proposed to amend § 507.10(a) of Part 507 (14 CFR Part 507), by adding the following airworthiness directive:

BOEING. Applies to all Models 707 and 720 Series Aircraft.

Compliance required as indicated.

During inspections of 720 Series aircraft, the four MS type bolts located at the top of the fitting and several other fasteners which attach the fin-body terminal fitting to the body Station 1505 bulkhead were found sheared. As a result of these failures, the following or an equivalent approved by FAA Aircraft Engineering Division, Western Region, shall be accomplished:

(a) Within 550 hours' time in service after the effective date of this AD, and thereafter at periods not to exceed 550 hours' time in service from the last inspection, visually inspect the four internal wrenching bolts, MS20005 or MS20006 located at the top of the fitting, which attach each fin-body terminal fitting to the 1505 bulkhead and check the torque tab within 130–180 inch-pounds. If any of the four MS type bolts are found torqued improperly, torque the bolts to 130–180 inch-pounds.

(b) If any of the four MS type bolts are failed inspect the remaining fasteners securing the fin-body terminal fitting to the body Station 1505 bulkhead for looseness by tapping or torquing.

(c) If any of the bolts or fasteners are found failed or loose, replace in accordance with the instructions in the applicable FAA approved Boeing Structural Repair Manual, or Service Bulletin No. 1975(R-1) or later FAA approved revisions before further flight.

(d) Within 6,000 hours' time in service after the effective date of this AD, accomplish the modification specified in Boeing Service Bulletin No. 1975(R-1), or later FAA-approved revisions.

(e) When the modification required by (d) is accomplished, the repetitive inspection and torquing of bolts specified in (a) and (b) may be discontinued.

(f) Upon request of the operator, an FAA maintenance inspector, subject to prior approval of the Chief, Aircraft Engineering Division, FAA Western Region, may adjust the repetitive inspection intervals specified in this AD to permit compliance at an established inspection period of the operator if the request contains substantiating data to justify the increase for such operator.

(Boeing Service Bulletin No. 1975(R-1) covers this same subject.)

Issued in Washington, D.C., on June 8, 1964.

W. LLOYD LANE,
Acting Director,
Flight Standards Service.

[F.R. Doc. 64-5860; Filed, June 12, 1964; 8:46 a.m.]

Notices

ATOMIC ENERGY COMMISSION

STATE OF NORTH CAROLINA

Proposed Agreement for Assumption of Certain AEC Regulatory Authority

Notice is hereby given that the U.S. Atomic Energy Commission is publishing for public comment, prior to action thereon, a proposed agreement received from the Governor of the State of North Carolina for the assumption of certain of the Commission's regulatory authority pursuant to section 274 of the Atomic Energy Act of 1954, as amended.

A résumé, prepared by the State of North Carolina and summarizing the State's proposed program, was also submitted to the Commission and is set forth below as an appendix to this notice. Appendixes referenced in the appendix are included in the complete text of the program. A copy of the program, including proposed North Carolina regulations, is available for public inspection in the Commission's Public Document Room, 1717 H Street NW., Washington, D.C., or may be obtained by writing to the Director, Division of State & Licensee Relations, United States Atomic Energy Commission, Washington 25, D.C. All interested persons desiring to submit comments and suggestions for the consideration of the Commission in connection with the proposed agreement should send them, in triplicate, to the Secretary, U.S. Atomic Energy Commission, Washington 25, D.C., within 30 days after initial publication in the FEDERAL REGISTER.

Exemptions from the Commission's regulatory authority which would implement this proposed agreement, as well as other agreements which may be entered into under section 274 of the Atomic Energy Act, as amended, were published as Part 150 of the Commission's regulations in FEDERAL REGISTER issuance of February 14, 1962; 27 F.R. 1351. In reviewing this proposed agreement, interested persons should also consider the aforementioned exemptions.

Dated at Washington, D.C., this 20th day of May 1964.

For the Atomic Energy Commission.

WOODFORD B. MCCOOL,
Secretary to the Commission.

Proposed Agreement Between The United States Atomic Energy Commission and the State of North Carolina for Discontinuance of Certain Commission Regulatory Authority and Responsibility Within the State Pursuant to Section 274 of the Atomic Energy Act of 1954, as Amended

Whereas, The United States Atomic Energy Commission (hereinafter referred to as the Commission) is authorized under section 274 of the Atomic Energy Act of 1954, as amended (hereinafter referred to as the Act) to enter into agreements with the Governor of any State providing for discontinuance of the regulatory authority of the Commission within the State under Chapters 6, 7, and 8 and section 161 of the Act with respect to byproduct materials, source materials, and special nuclear materials in quantities not sufficient to form a critical mass; and

Whereas, The Governor of the State of North Carolina is authorized under North Carolina General Statutes (G.S. 104C–5; 1963, c. 1211) to enter into this Agreement with the Commission; and

Whereas, The Governor of the State of North Carolina certified on ---------- that the State of North Carolina (hereinafter referred to as the State) has a program for the control of radiation hazards adequate to protect the public health and safety with respect to the materials within the State covered by this Agreement, and that the State desires to assume regulatory responsibility for such materials; and

Whereas, The Commission found on ------------ that the program of the State for the regulation of the materials covered by this Agreement is compatible with the Commission's program for the regulation of such materials and is adequate to protect the public health and safety; and

Whereas, The State recognizes the desirability and importance of maintaining continuing compatibility between its program and the program of the Commission for the control of radiation hazards in the interest of public health and safety; and

Whereas, The Commission and the State recognize the desirability of reciprocal recognition of licenses and exemption from licensing of those materials subject to this Agreement; and

Whereas, This Agreement is entered into pursuant to the provisions of the Atomic Energy Act of 1954, as amended;

Now, Therefore, It is hereby agreed between the Commission and the Governor of the State, acting in behalf of the State, as follows:

Article I. Subject to the exceptions provided in Articles II, III, and IV, the Commission shall discontinue, as of the effective date of this Agreement, the regulatory authority of the Commission in the State under Chapters 6, 7, and 8, and section 161 of the Act with respect to the following materials:

A. Byproduct materials;

B. Source materials; and

C. Special nuclear materials in quantities not sufficient to form a critical mass.

Article II. This Agreement does not provide for discontinuance of any authority and the Commission shall retain authority and responsibility with respect to regulation of:

A. The construction and operation of any production or utilization facility;

B. The export from or import into the United States of byproduct, source, or special nuclear material, or of any production or utilization facility;

C. The disposal into the ocean or sea of byproduct, source, or special nuclear waste materials as defined in regulations or orders of the Commission;

D. The disposal of such other byproduct, source, or special nuclear material as the Commission from time to time determines by regulation or order should, because of the hazards or potential hazards thereof, not be so disposed of without a license from the Commission.

Article III. Notwithstanding this Agreement, the Commission may from time to time by rule, regulation, or order, require that the manufacturer, processor, or producer of any equipment, device, commodity, or other product containing source, byproduct, or special nuclear material shall not transfer possession or control of such product except pursuant to a license or an exemption from licensing issued by the Commission.

Article IV. This Agreement shall not affect the authority of the Commission under subsection 161 b. or i. of the Act to issue rules, regulations, or orders to protect the common defense and security, to protect restricted data or to guard against the loss or diversion of special nuclear material.

Article V. The Commission will use its best efforts to cooperate with the State and other agreement states in the formulation of standards and regulatory programs of the State and the Commission for protection against hazards of radiation and to assure that State and Commission programs for protection against hazards of radiation will be coordinated and compatible. The State will use its best efforts to cooperate with the Commisison and other agreement states in the formulation of standards and regulatory programs of the State and the Commission for protection against hazards of radiation and to assure that the State's program will continue to be compatible with the program of the Commission for the regulation of like materials. The State and the Commission will use their best efforts to keep each other informed of proposed changes in their respective rules and regulations and licensing, inspection and enforcement policies and criteria, and to obtain the comments and assistance of the other party thereon.

Article VI. The Commission and the State agree that it is desirable to provide for reciprocal recognition of licenses for the materials listed in Article I licensed by the other party or by any agreement State. Accordingly, the Commission and the State agree to use their best efforts to develop appropriate rules, regulations, and procedures by which such reciprocity will be accorded.

Article VII. The Commission, upon its own initiative after reasonable notice and opportunity for hearing to the State, or upon request of the Governor of the State, may terminate or suspend this Agreement and reassert the licensing and regulatory authority vested in it under the Act if the Commission finds that such termination or suspension is required to protect the public health and safety.

Article VIII. This agreement shall become effective on ------------, and shall remain in effect unless, and until such time as it is terminated pursuant to Article VII.

Policies and Procedures Applicable to North Carolina Regulations for Protection Against Radiation

Foreword. Section 274 of the Atomic Energy Act of 1954, as amended, authorizes the United States Atomic Energy Commission to enter into an agreement with the Governor of a State to transfer to the State certain licensing and control of byproduct, source, and special nuclear materials in quantities not sufficient to form a critical mass. The North Carolina State Board of Health (hereafter referred to as "the Agency") has been designated by the North Carolina General Assembly and is prepared to accept this responsibility. To that end the Agency hereby presents a narrative description of its proposed program for the control of sources of ionizing radiation, including naturally occurring isotopes and certain radiation producing machines.

The regulatory program for control of sources of ionizing radiation in North Carolina, presented here in some detail, will be conducted in such a manner as to protect effectively the public health and safety, and to further the economic growth of the State by encouraging the safe and proper utilization of radiation for peaceful purposes. The program is compatible with the regulatory program of the United States Atomic Energy Commission and will be maintained so as to ensure this compatibility. Uniformity with the regulatory programs of other agreement States will be maintained so far as possible.

The Agency places primary and specific responsibilities for radiation protection upon those persons licensed or registered for sources of radiation, and upon those furnishing designated equipment servicing and services. The Agency has adequate authority and capability to assure compliance with the North Carolina Regulations for Protection Against Radiation.

Statutory Authority. In 1959 the North Carolina General Assembly enacted authority to the Agency (G.S. 104C) to adopt reasonable rules and regulations to provide protection against hazard from radioactivity and ionizing radiation; to require registration of persons possessing or using specified sources of radiation; to enter premises to determine whether applicable laws and regulations are being properly observed; to provide an inspection service and to make surveys (Appendix I). A 1963 amendment to G.S. 104C designated the North Carolina State Board of Health as the Agency which shall provide by rule or regulation for licensing of byproduct, source, special nuclear materials, or devices or equipment utilizing such materials, and for amendment, suspension or revocation of licensees; grants specific authority to the Agency for related protective activities; authorizes the Agency to provide for recognition of other State and Federal licenses as it may deem desirable; authorizes the Governor "to enter into agreements with the Federal Government providing for discontinuance of certain of the Federal Government's responsibilities with respect to sources of ionizing radiation and the assumption thereof by this State" (Appendix II).

The Agency has multiple other general and specific statutory authorities and responsibilities related to the 1959 Act and its 1963 amendment (copies available upon request to the Agency).

History. The North Carolina program for protection against radiation has developed progressively. A committee, advisory to the State Board of Health, on radiation protection was established early in 1958. During the same year this Agency began organizing a State Radiological Emergency Team, which became functional in September 1961. A voluntary State committee, advisory to the Governor on nuclear energy, was also established in 1958. These related actions are reflected in the 1959 North Carolina Atomic Energy, Radioactivity and Ionizing Radiation Law (Appendix I).

This Act established the State policy to promote sound and healthy programs for progressive use of atomic energy in the State, while protecting the public's interests and insuring public health and safety. The Act established the North Carolina Atomic Energy Advisory Committee with six subcommittees on agriculture, education and research, industry and labor, medicine and public health, power, and radiation standards (lists of the Committee and Subcommittee memberships are available upon request to the Agency). The Act assigned specific authority and duties to the State Board of Health.

The State Health Director in 1960 initiated the organization, assured interim staffing, and assigned developmental responsibilities for the State Radiological Health Program. All have been brought up to date recently.

Previous independent activities have included: The establishment in 1952 at North Carolina State College in Raleigh for educational and research purposes the first reactor not owned by the Federal Government; voluntary registration of radiation sources; setting up of patterns for occupational surveillance; actively developed environmental surveillance; readiness to meet reported radiation accidents and emergencies; providing the laboratory services required to support each of these. An orderly equipment procurement program has been implemented to make essential equipment available as staffing progressed.

One of the earliest acts of the North Carolina Atomic Energy Advisory Committee was giving support to the State Health Director's proposal in June, 1960 as he sought United States Public Health Service funds, which resulted in the establishment of a five-year graduate program in Radiological Health (Master's Degree) at the University of North Carolina, School of Public Health, administered entirely by that school. Another early Committee activity was support of the State Health Director in his request to the United States Atomic Energy Commission, which resulted in a contract to establish the North Carolina Institute in Fundamentals of Radiation and Radiological Protection at North Carolina State College and the School of Public Health, 1962–1963. Forty-eight State and local agency personnel were enrolled in the five courses. The Committee has reviewed the many studies, proposals, and recommendations of the State Board of Health in development of the State's radiation protection program. Its subcommittees have been, and will continue, available to the Agency at all times in furnishing advisory and co-ordinating assistance.

In late 1960 a program jointly developed by the State Board of Health with the State's medical, dental, hospital, and veterinary medical associations permitted the voluntary registration of radiation sources in the State before mid-1961. Supplemented by a detailed study of copies of licenses issued by the United States Atomic Energy Commission, and by a Statewide voluntary survey of dental X-ray machines (Surpak), more than three-fourths of all radiation sources in North Carolina have been identified, a bulletin was published in November 1963 listing the known sources so that health, civil defense, law enforcement, and fire prevention and fire fighting services as well as professional, safety, insurance, labor, compensation, and other related personnel can be informed of the nature and extent of most of the existing potential radiation hazards in each community. The Radiological Defense Service of the State Civil Defense Agency, although independent in authority and responsibility, is directed by the same personnel who direct the continuing day-to-day Radiological Health Programs. Both programs are closely co-ordinated and reviewed periodically with the State's law enforcement authorities.

An Agency environmental radiation surveillance program, begun in 1958, checks water supplies for 120 communities periodically, establishing factually the existing background radioactivity in the waters. This program has been evaluated and detailed results published annually, so that the current and future surveillance is on a more practical and authoritative (technical) basis. (Copies of pertinent reports are available upon request to the Agency). Concurrently, the State has long participated with the United States Public Health Service in nationwide, air, milk, and water surveillance network programs. Within the past year the State's independent program has expanded in the realms of air, water, milk surveillance, and food sampling.

In the realm of occupational surveillance, up to now, there has been no compulsory licensing, registration, or inspection. In 1949, shoe-fitting fluoroscopes throughout the State were inspected and their hazards reported to owners who removed them. By 1951, X-ray facilities of several local health departments were inspected and surveyed wherever requested. In 1961–1962, all X-ray facilities of the 100 local health departments in the State were surveyed, demonstrating widespread need for attention to personnel monitoring, proper collimation and filtration, operator shielding, and room shielding. During 1962–1963, with United States Public Health Service support, a Statewide Surpak survey of dental X-ray machines achieved voluntary participation by ninety percent of the 1,462 known dentists; only 20 percent revealed no apparent need for correction. Almost all deficiencies were readily corrected by the dentists' use of fittings furnished to them free. Later, jointly with the North Carolina State Veterinary Medical Association, voluntary survey of Veterinarians' X-ray facilities was undertaken. This has resulted in widespread improvement of personnel monitoring, and correction of improper collimation and filtration.

Occupational surveillance over radioactive materials by the Agency's personnel has involved accompanying Atomic Energy Commission inspectors on essentially all inspections during the past four years. These same State personnel will inspect for the State under this program. In addition all Civil Defense Radiological Defense Service Cobalt 60 source sets have been independently inspected and leak-tested by these State personnel.

The State Radiological Emergency Team has been continuously available since September 1961 when the first issue of the team's procedural guide was published. The team's handbook is revised periodically, the last time, September 1963 (a copy is available upon request to the Agency). Thus, the professionally competent technical guidance by team members has been planned from the start, and continues co-ordinated, with State law enforcement and transportation authorities. Nine American Board certified medical radiologists are available to the team at all times as consultants in any medical care required for victims of radiation accidents.

To support the expanding activities the Agency's Laboratory Division has installed effective equipment, and the increased staff is kept currently abreast of new developments.

The radiation protection program has continued towards State participation under section 274 of the Atomic Energy Act of 1954, as amended. Timely changes have been made in priorities for various program activities in order to meet changing circumstances. For example, environmental surveillance could be and was expedited due to atmospheric testing fallout. Nevertheless, the whole program has been functional since March 5, 1963.

The biennial program to June 30, 1965, is published and is revised annually. It will provide surveillance over environmental and occupational radiation sources, readiness for handling the effects of predictable accident/incident, and laboratory supports to all of these activities.

North Carolina Regulations for Protection Against Radiation, compatible with section 274 and the recommendations of the United States Atomic Energy Commission, United States Public Health Service, and the Council of State Governments, have been approved by the North Carolina Atomic Energy Advisory Committee, the State Board of Health, and the Governor of North Carolina (appendix III). Interested parties have had the opportunity to participate in public hearings on licensing and regulatory activities of the

Agency, and have suggested or commented upon the Agency's proposed regulations.

Standards. The standards prescribed by the Agency are included in North Carolina Regulations for Protection Against Radiation (Appendix III). These standards are equivalent to and compatible with current United States Atomic Energy Commission standards and those of the current agreement states. The standards pertaining to transportation are consistent with rules and regulations of the Interstate Commerce Commission, Federal Aviation Agency, United States Coast Guard, and Post Office Department; the standards pertaining to intrastate transportation are consistent with the same rules and regulations, and with State laws and regulations coming under statutory jurisdiction of all North Carolina agencies. All regulatory requirements are reviewed by the North Carolina Atomic Energy Advisory Committee prior to submission to the Governor for the approval required by statute.

Operating Procedures. The Agency's program for meeting statutory responsibilities is outlined hereafter:

(a) *Licensing.* Licenses will be required for all persons who possess or use in North Carolina radioactive materials in excess of exempt quantities and concentrations. Both general and specific licenses will be issued by the Agency and the criteria for the issuance and renewal of licenses will be the same as used by the United States Atomic Energy Commission. Provisions have been made in the regulations for exemption of certain quantities, concentrations, and devices; e.g., any person may receive, possess, or use products or materials containing radioisotopes in amounts or concentrations not in excess of those listed in the published exempt schedule.

The Agency will issue general licenses under specified circumstances where more stringent control by specific licenses is found to be unnecessary to protect the public health and safety. General licenses will be effective without either the filing of applications with the Agency or the issuance of documents by the Agency to a specific person. In addition to the generally licensed or exempt quantities, certain devices containing radioactive materials which have a built-in high safety factor, and will be safe for use by persons not trained in radiation protection, will be generally licensed.

Specific licensing procedures will involve both the evaluation of the possible radiation hazards and the determination of the adequacy of the radiation controls specifically proposed for application by the license applicants. The required controls will vary with the type of radioactive material(s) under consideration and the proposed use(s). Standards and licensing guides compatible with those used by the United States Atomic Energy Commission will be applied in making these evaluations. No standards more restrictive than those established by the Atomic Energy Act of 1954, and amendments, will be imposed by the Agency.

The Agency's regulations require the following for the issuance of a specific license:

1. The applicant shall be qualified by training and experience to possess and use the material safely and for the proposed purpose.

2. Facilities and equipment of the applicant shall be adequate to protect.

3. The location of the proposed activity shall be suitable for the purpose.

The Agency will require sufficient information submitted by an applicant to provide full knowledge of the proposed program, and this will be used as the basis to determine whether the applicant will be able to comply with the radiation safety regulations. A license will be issued only if the training and experience, facilities and equipment, and proposed operating procedures appear to be adequate for radiation protection, considering the type of material, levels of activity, and the proposed use.

A visit will be made prior to the issuance of a license when this is deemed necessary to make an on-the-spot evaluation of facilities and equipment and of the proposed radiation protection program.

License conditions or requirements will be included in a specific license to cover significant matters or special needs not expressly defined in the pertinent sections of the regulations. The regulations provide the bases for modification, revocation, and termination of licenses.

An Agency Health Physicist will make the initial review and evaluate each application for license. Applications involving significant environmental hazards may be referred to the Sanitary Engineering Division, those involving significant occupational or inplant hazards to employees may be referred to the Occupational Health Section, for review, comment, and recommendation prior to issuance of a license.

Where indicated, applications involving human use will be referred to the Agency's Medical Isotopes Advisory Group for evaluation, comment, and recommendation. For example, such instances may include: *1.* Circumstances in which the licensing staff has no established precedent for the usage, dosage, or procedure proposed by the applicant; *2.* Where an applicant proposes selection of unusual isotope(s), or excessive or unusual dosage or administration, or procedure, according to known previous experience; *3.* Where the applicant appears to have insufficient training and/or no prior experience in handling isotopes for human usage; *4.* Where currently available information reveals little or no such human use up to now. Under other unusual circumstances, advisory assistance is available and will be sought from qualified consultants.

(b) *Registration.* The Agency is authorized to require the registration of radiation machines (Appendix I) except some 700 X-ray machines (hospital) subject to the provisions of G.S. 131–126.3 (1963, c. 66). Most sources of radiation, including the hospital X-ray facilities and materials which will be licensed by the Agency, have already been voluntarily registered with the Agency. Every person who furnishes or offers to furnish in North Carolina any service or equipment servicing to Agency licensees or registrants will be required to register with the Agency.

(c) *Inspections*—(1) *Licensees.* There will be five types of physical inspections made of radioisotope licensees or license applicants, designated according to their primary purposes. Each of the following types of inspection will be undertaken to the extent the existing circumstances dictate:

1. Prelicensing inspection. At the time of the review of an applicant's proposed program, it will be determined whether or not the quantities and forms of the materials to be used and the scope of the proposed program will justify a prelicensing inspection. This type of inspection will be made to determine if the applicant is capable of conducting his program safely and to obtain additional information needed or desired by those responsible for approving the applicant for license.

2. Initial inspections. After a new license to possess and use material has been granted, the inspection staff will arrange with management for an initial inspection. This type of inspection normally will be announced so that the inspectors will be assured that the authorized radioactive materials will have been obtained, and a use program is in progress.

3. Reinspection. Reinspections will be made of continuing programs subsequent to a previous inspection and may be announced or unannounced. A program is considered continuous even though a new license number may have been assigned.

4. Followup inspections. When items of noncompliance noted on previous inspections justify, followup inspections will be made in addition to others routinely scheduled, to determine the status of corrective action taken by the licensee. This type of inspection will be justified and scheduled only when the items of noncompliance present a potentially significant hazard to the licensee, his employees, or the public, or when management has demonstrated that it may not intend to, or may be unable to, take the corrective actions necessary.

5. Request inspections. The inspection staff will respond to requests by management, a local health director, or other responsible person, for inspection of facilities when the advisory assistance requested cannot be satisfactorily given by means of regular communication. Request inspections may also serve as reinspections if the time of inspection is compatible with the priority schedule established for the licensee. Inspections will also be made on the request of State or local authorities having legitimate cause.

(2) *Registants of X-ray equipment.* There will be four types of physical inspection made of the facilities of registrants of X-ray equipment, utilizing instrumentation:

1. Initial inspections. This type of Agency-initiated inspection normally will be announced so that the registrant can cooperate with the inspector conveniently and beneficially to himself.

2. Reinspections. This type of inspection normally will be announced, as with initial inspections, and usually because of a change of significant nature in the X-ray facility, equipment, or procedures.

3. Followup inspections. This type of inspection will be justified and scheduled only when items of noncompliance, if uncorrected, can create a real and unauthorized radiation exposure of the facility's personnel or the public.

4. Request inspections. This type of inspection, with or without prior announcement, usually will respond to requests by owners, users, local health and other authorities, or other responsible persons, when the advisory assistance requested concerning significant problems cannot be given satisfactorily by means of regular communications.

(3) *Schedule of inspections and surveys.* All types of inspections may be made unannounced if the purpose of the inspection can be served and all desired observations can be made satisfactorily. When advisable to conserve travel time and expense of inspecting personnel or to facilitate normal activities of X-ray equipment registrants, the management or user of a facility may be notified of an impending inspection and an appointment made.

1. Inspection schedule for licensees. The schedule for initial inspection and reinspections of licensees will be determined by priorities established for each license at the time the license is granted. Priorities will be assigned according to the category of use and the scope of the program. Priorities assigned prior to initial inspection will be considered tentative until confirmed after inspection. Priorities may be changed by amendments of license during the course of a program when such changes seem advisable after receipt of notice of a change in the scope of the program or of a change in the category of use. If more than one category is involved, priority will be based on the more restrictive category.

Initial inspection and reinspection schedules will be determined by priorities. Priorities will be determined by the degree of hazard involved with the use of materials in each case.

2. Inspection schedule for registrants of X-ray equipment. Allowing for economy, efficiency, and flexible adjustment to unpredictable circumstances, priorities of inspection of X-ray registrants will be given to the following order:

Priority I: Request inspections.

Priority II: Followup inspections.

Priority III: Initial inspections, undertaken geographically to conserve expense and personnel effort.

Priority IV: Reinspections.

(4) *Designated agency representatives.* Onsite initial inspections of programs and facilities of licensees, license applicants, and registrants always will be made by an Agency Health Physicist, or by designated authorized representatives of the Agency's Occupational Health Section who are qualified by experience and training in radiological health. Later inspections normally will be made by the same personnel. In addition, after approval by the State Board of Health in each instance, the Director, State Radiation Protection Program may designate in writing for a specified period of time a named public employee, e.g., of a State or local governmental agency, when qualified, as authorized representative of the agency, in accordance with section A/11(b), North Carolina Regulations for Protection Against Radiation. Prior to authorization by the Agency the individual qualifications for the designated purpose will be reviewed and proven at least equal to those of Agency incumbent personnel. Conduct of all inspections and the resulting reports will be subject to Agency supervision and to review by the Public Health Physicist and the Director of the State Radiation Protection Program. The Agency's Public Health Physicist will act as consultant and render technical advice to all authorized representatives of the Agency.

(5) *Conduct of inspections.* The Agency authorized representative making an inspection will interview the licensee, management, or registrant, and discuss the complete program in considerable detail.

The Agency authorized representative will be prepared with proper instrumentation to make all necessary radiation measurements in work areas and at the completion of the physical and records survey, the inspector will discuss his findings with the licensee or registrant and point out any items of noncompliance noted. He will assist the licensee or registrant by explaining the corrections the inspector has observed to be needed in the program.

(6) *Inspection reports.* A summary report of every inspection will be prepared to include a description of the program, records, violations, and other pertinent remarks, a copy of which will be furnished the licensee or registrant, and a copy filed by the Agency.

(d) *Accidents and incidents.* Investigation at the site of a radiological accident or incident will be made promptly in detail to determine the cause of the incident, in accordance with the provisions contained in the Handbook, North Carolina State Radiological Emergency Team (copy available upon request to the Agency). Agency authorized representatives will discuss with those persons responsible, measures to prevent additional incidents. The Agency has statutory authority to control effectively any incident and to protect adequately the public health and safety. Investigation of an incident should reveal whether or not any Agency action with or against the licensee is indicated.

(e) *Enforcement.* Status of compliance with the Agency's regulations will be determined by evaluation of reports of inspections of licensees' and registrants' activities.

If no items of noncompliance are observed at the time of an inspection, each licensee or registrant will be so informed. If only minor items of noncompliance are observed and the licensee or registrant agrees at the time of the inspection to correct these, the licensee or registrant will be informed by letter of the items of noncompliance and that the effectiveness of corrective actions undertaken will be reviewed at the time of the next inspection.

If the inspection report shows noncompliance of potentially significant nature, the licensee or registrant will be required to notify the Agency promptly in writing as to every corrective action taken and the date completed. Thereafter, a prompt followup inspection may be made to insure that the necessary corrective action has been accomplished. If the written notification to the Agency does not explain satisfactorily a licensee's noncompliance, and also assure that further predictable violations will be prevented, the Agency may issue an order to show cause why the license should not be terminated or otherwise modified. If conditions observed during an inspection create a serious potential or actual hazard, the inspector will report immediately to the Agency by telephone. Enforcement action, such as an order by the Agency to the licensee or registrant to take immediate corrective action, may then be taken without delay. The Agency is authorized to impound sources of ionizing radiation under specified circumstances.

Willful noncompliance, or a need for extensive Agency action to correct or control deficiencies or acts of noncompliance, are expected to be unusual or of rare occurrence. Every effort by the Agency will be extended towards securing voluntary co-operation and compliance, and thereby creating little demand for legal enforcement.

A hearing may be held upon the request of any person whose interest may be affected by enforcement proceedings.

Delegation of Authority—(a) *Chain of command.* As approved by the State Board of Health, the State Health Director has authority to delegate the pertinent responsibilities. He has done this by delegation of administrative direction to specified staff members, and to certain personnel devoting full time and part time for implementing the program. The Director of the State's Radiation Protection Program directs the planning and implementation of the entire program, coordinated between the division directors concerned. Implementation of the respective responsibilities is undertaken by the Chief, Radiation Protection Section for Public Health Physics guidance and activities; by the Director, Sanitary Engineering Division for environmental radiation surveillance; by the Chief, Occupational Health Section for occupational radiation surveillance; by the Chief, State Radiological Emergency Team for response to and control of accidents; and by the Director, Laboratory Division for all laboratory services required to support these operational segments of the program. Hence, the chain of command proceeds directly: from the State Board of Health to the State Health Director, to the program Director, to the Director, Sanitary Engineering Division, and to the Director, Laboratory Division. The program director administers directly the activities of the Radiation Protection Section, the Occupational Health Section, and the State Radiological Emergency Team.

(b) *Delegation of authority.* The authority and responsibility for administering North Carolina Regulations for Protection Against Radiation, covering the statutory licensing of byproduct, source, special nuclear materials, or devices or equipment utilizing such materials, has been assigned to the Director, State Radiation Protection Program. As he directs, applications for licenses will be approved or disapproved. He will issue denials for cause, or denials without prejudice. He may terminate a license, after opportunity is offered the licensee for a hearing, due to failure to correct items of noncompliance, or for other justified cause, after specific approval by the State Health Director in each instance. Under his administrative control the Health Physicist will provide technical assistance and consultation, to him and to all other Agency personnel administering and implementing the State Radiation Protection Program and the North Carolina Regulations for Protection Against Radiation.

Personnel and staffing. Sufficient and qualified Agency staff and consultants are available:

(a) *Agency staff.* Individual staff qualifications reflect the necessary education, training, and experience to ensure competent administration and implementation of the program (Appendix IV). All future replacements of incumbents, or employment to fill new vacant positions, will follow close scrutiny to ensure qualifications at least equal to those of incumbents.

(b) *Consultants.* The Agency and its State Radiological Emergency Team can call upon 20 qualified consultants voluntarily available within the State to advise upon and assist in the handling of any unusual or complex problem or serious hazard related to this program:

(1) Six general program consultants include a Board-Certified Industrial Hygiene Engineer specializing in radiological health; an experienced chemist (Ph. D.) specializing in nuclear, tracer, and radiation chemistry; a Fellow of the American Academy of Oral Roentgenology; a physicist (Ph. D.) experienced in laboratory equipment design and applications to nuclear science and engineering and directing a recognized research laboratory; two experienced radiological safety officers of two recognized graduate educational and research institutions

(2) Nine Board Certified Medical Radiologists, all recognized in the diagnostic and therapeutic aspects of X-ray, radium and medical isotopes involving human use

(3) Six members of the Agency's Medical Isotopes Advisory Group, including three Board-Certified Radiologists experienced with medical isotopes; two Board-Certified Health Physicists experienced in educational, research, and medical radiation protection and safety programs; a radiation biologist (has just completed Ph. D. requirements) experienced in and chief of medical physics at a third recognized North Carolina graduate educational and research institution.

Regulations. The Agency has statutory authority to administer the applicable regulations (Appendix III), which will become effective upon the effective date of the agreement between the Governor of North Carolina and the United States Atomic Energy Commission. Interested parties have timely opportunity to participate in public hearings on licensing and regulatory activities of the Agency.

Budget. The biennial budget for fiscal years 1964 and 1965 as originally approved provides sufficiently for a sound program. Minor salary increases for clerical personnel have been provided by administrative action. The actual expenditures during fiscal year 1963 approximated those occurring during 1964 (a budget summary is available upon request submitted to the Agency).

Funds are sufficient through fiscal year 1965 for 14 full-time personnel, 12 currently employed. Nine other professional personnel devote up to 50 percent part time to this program. New position vacancies will permit timely employment of two full-time inspecting personnel for radioactive materials. This will provide staff equivalent to four full-time radiation inspectors. Although currently qualified, the existing staff regularly will attend appropriate professional, conference, seminar, and short-course training to maintain and improve administrative and technical competence. Their necessary travel for training and daily duties is assured. Up-to-date survey and laboratory equipment has been procured. An equipped instrument maintenance shop is manned by a well-qualified employee. A high-level survey instrument calibration facility will be functional July 1, 1964.

Equipment. All necessary equipment has been procured and is functional (Appendix V). In addition, laboratory facilities at Duke University, North Carolina State College, University of North Carolina School of Public Health, and North Carolina Research Triangle Institute Isotopes Development Laboratory, are available to the Agency for limited supplementary counting and analyses under unusual demands. The program director keeps himself informed of the locations of all State Civil Defense Agency instruments and 39 Cobalt 60 source sets, as Chief, Radiological Defense Service.

The Agency is licensed for and has a Radiac Calibrator (120-curie Cs-137) for use in an established high-level survey instrument calibration facility. A suitable X-ray facility is planned, for variable-level calibration of the Agency's X-ray survey instruments. Both calibration facilities will be utilized also in special studies contributing to the program. The Agency has a well-equipped electronics maintenance shop administered by a qualified electronics specialist. All Agency equipment is thoroughly inspected and tested, repaired when necessary, and calibrated periodically.

Sample Forms. In addition to notice to employees and occupational exposure record forms, found at the end of Part C of the Agency's draft regulations (Appendix III), sample forms have been drafted for applications, licenses, and registration (Appendix VI).

[F.R. Doc. 64-5171; Filed, May 22, 1964; 8:47 a.m.]

DEPARTMENT OF THE TREASURY

Bureau of Customs

[AA 643.3-p]

APPLE JUICE FROM CANADA

Purchase Price; Foreign Market Value

JUNE 9, 1964.

Pursuant to section 201(b) of the Antidumping Act, 1921, as amended (19 U.S.C. 160(b)), notice is hereby given that there is reason to believe or suspect, from information presented to me, that the purchase price of apple juice, in 46-ounce tins, imported from Canada, manufactured by Sun-Rype Products Limited, Kelowna, British Columbia, Canada, is less, or likely to be less, than the foreign market value, as defined by sections 203 and 205, respectively, of the Antidumping Act, 1921, as amended (19 U.S.C. 162 and 164).

Customs officers are being authorized to withhold appraisement of entries of apple juice, in 46-ounce tins, from Canada, manufactured by Sun-Rype Products Limited, Kelowna, British Columbia, Canada, pursuant to § 14.9 of the Customs Regulations (19 CFR 14.9).

The allegation in this case was received on April 23, 1964, and was made by the firm of Tree Top, Inc., Omak, Washington.

[SEAL] PHILIP NICHOLS, Jr.,
Commissioner of Customs.

[F.R. Doc. 64-5882; Filed, June 12, 1964; 8:47 a.m.]

DEPARTMENT OF THE INTERIOR

Office of the Secretary

[Order 2508, Amdt. 60]

COMMISSIONER OF INDIAN AFFAIRS

Delegation of Authority With Respect to Authority Under Specific Acts

Section 30 of Order 2508, as amended (20 F.R. 3834, 5106; 21 F.R. 7027, 7655; 24 F.R. 272; 25 F.R. 436, 575, 729, 1385, 1994, 4655, 7192, 8892; 26 F.R. 6944; 27 F.R. 2328, 11560; 28 F.R. 1072, 2199, 2927, 5687, 12633), is further amended by the addition of two new subparagraphs to read as follows:

SEC. 30. *Authority under specific acts.* (a) In addition to any authority delegated elsewhere in this order, the Commissioner of Indian Affairs, except as provided in paragraph (b) of this section, is authorized to perform the functions and exercise the authority vested in the Secretary of the Interior by the following acts or portions of acts or any acts amendatory thereof:

* * * * *

(26) The Act of December 11, 1963 (P.L. 88-196, 77 Stat. 349) authorizing the sale, exchange, or mortgage of isolated tracts of tribal land on the Rosebud Sioux Indian Reservation, South Dakota.

(b) The authority granted in paragraph (a) of this section shall not include:

* * * * *

(11) The authority to issue land patents under the Act of December 11, 1963 (P.L. 88-196, 77 Stat. 349).

STEWART L. UDALL,
Secretary of the Interior.

JUNE 5, 1964.

[F.R. Doc. 64-5871; Filed, June 12, 1964; 8:47 a.m.]

[Order 2765, Amdt. 8]

COMMISSIONER OF RECLAMATION

Delegation of Authority

Paragraph (9) of section 1 of Order 2765 as amended (23 F.R. 10570, 26 F.R. 3575, 28 F.R. 5273) is amended to read as follows:

SECTION 1. *Authority.* Except as provided in section 2 of this order, the Commissioner of Reclamation is authorized to:

(a) Perform the functions and exercise the authority now or hereafter vested in the Secretary of the Interior, or in the Department of the Interior, by:

* * * * *

(9) The Falcon Dam Act of June 18, 1954 (68 Stat. 255, as amended; 77 Stat. 475);

STEWART L. UDALL,
Secretary of the Interior.

JUNE 5, 1964.

[F.R. Doc. 64-5872; Filed, June 12, 1964; 8:47 a.m.]

FRANKLIN STUART FEHR

Statement of Financial Interests

JUNE 9, 1964.

Pursuant to section 302(a) of Executive Order 10647, the following information on a WOC appointee in the Department of the Interior is furnished for publication in the FEDERAL REGISTER:

Name of appointee. Franklin Stuart Fehr.

Name of employing agency. Department of the Interior, Office of Assistant Secretary for Water and Power Development.

The title of the appointee's position. Alternate Deputy Director, Defense Electric Power Area 3.

The name of the appointee's private employer or employees. Metropolitan Edison Company.

The statement of "financial interests" for the above appointee is set forth below.

STEWART L. UDALL,
Secretary of the Interior.

Appointee's Statement of Financial Interests

In accordance with the requirements of section 302(b) of Executive Order 10647, I am filing the following statement for publication in the FEDERAL REGISTER:

(1) Names of any corporations of which I am, or had been within 60 days preceding my appointment, on May 12, 1964, as Alternate Deputy Director, Defense Electric Power Area 3, Office of Assistant Secretary, Water and Power Development, an officer or director:

None.

(2) Names of any corporations in which I own, or did own within 60 days preceding my appointment, any stocks, bonds, or other financial interests:

Metropolitan Edison Co., 3.8 percent Preferred, 3 shares.

First National Bank of Bernville, Common, 4 shares.

New York State Electric & Gas Corp., Common, 8 shares.

General Public Utilities Corp., Common, 84 shares.

(3) Names of any partnerships in which I am associated, or had been associated within 60 days preceding my appointment:

None.

(4) Names of any other businesses which I own, or owned within 60 days preceding my appointment:

None.

FRANKLIN STUART FEHR.

JUNE 3, 1964.

[F.R. Doc. 64-5876; Filed, June 12, 1964; 8:47 a.m.]

DEPARTMENT OF AGRICULTURE

Agricultural Stabilization and Conservation Service

SUGARCANE IN LOUISIANA

Notice of Hearing on Wages and Prices and Designation of Presiding Officers

Pursuant to the authority contained in sections 301(c)(1) and 301(c)(2) of the Sugar Act of 1948, as amended (61 Stat. 929; 7 U.S.C. 1131), and in accordance with the rules of practice and procedure applicable to wage and price proceedings (7 C.F.R. 802.1 et seq.), notice is hereby given that a public hearing will be held in Houma, Louisiana, in the District Court Room, Terrebonne Parish Courthouse, on July 9, 1964, beginning at 10:00 a.m.

The purpose of such hearing is to receive evidence likely to be of assitance to the Secretary of Agriculture in determining (1), pursuant to the provisions of section 301(c)(1) of said Act, fair and reasonable wage rates for persons employed in the harvesting of the 1964 crop of sugarcane, and in the production and cultivation of sugarcane during the calendar year 1965, and (2), pursuant to the provisions of section 301(c)(2) of said Act, fair and reasonable prices for the 1964 crop of sugarcane to be paid, under either purchase or toll agreements, by producers who process sugarcane grown by other producers and who apply for payments under the Act.

In the interest of obtaining the best possible information, all interested persons are requested to appear at the hearing to express their views and present appropriate data in regard to wages and prices. While testimony on all pertinent points is desired, it is especially requested that witnesses be prepared to offer information and recommendations on the following matter regarding fair wages for fieldworkers and fair prices for sugarcane:

I. *Wages.* (a) Elimination of the 5 cent per hour differential in wage rates between harvesting work and production and cultivation work for tractor drivers.

(b) Elimination of piecework rates per ton for cutting sugarcane.

(c) Regrouping of harvest worker classification and evaluation of rate differentials to provide a simplified basic minimum wage structure.

II. *Prices.* Periods to be used to determine the seasons' average prices of raw sugar and blackstrap molasses.

The hearing, after being called to order at the time and place mentioned herein, may be continued from day to day within the discretion of the presiding officers and may be adjourned to a later day or to a different place without notice other than the announcement thereof at the hearing by the presiding officers.

D. E. McGarry, Ward S. Stevenson, and W. N. Garrott are hereby designated as presiding officers to conduct either jointly or severally the foregoing hearing.

Signed at Washington, D.C., on June 10, 1964.

E. A. Jaenke,
Acting Administrator, Agricultural Stabilization and Conservation Service.

[F.R. Doc. 64-5900; Filed, June 12, 1964; 8:49 a.m.]

Office of the Secretary

CALIFORNIA

Extension of Period for Emergency Loans

For the purpose of making emergency loans pursuant to section 321 of the Consolidated Farmers Home Administration Act of 1961 (7 U.S.C. 1961), it has been determined that in the hereinafter-named counties in the State of California, the natural disasters for which said counties were designated (26 F.R. 5079, 6609) have resulted in a continuing need in those counties for agricultural credit not readily available from commercial banks, cooperative lending agencies, or other responsible sources.

CALIFORNIA

El Dorado.
Imperial.
Placer.
Tulare.

Designations of said counties were previously extended by extensions published in 27 F.R. 5775, 6240, and 28 F.R. 6097.

Pursuant to the authority set forth above, emergency loans will not be made in the above-named counties after June 30, 1965, except to applicants who previously received emergency or special livestock loan assitance and who can qualify under established policies and procedures.

Done at Washington, D.C., this 9th day of June 1964.

Orville L. Freeman,
Secretary.

[F.R. Doc. 64-5874; Filed, June 12, 1964; 8:47 a.m.]

DEPARTMENT OF COMMERCE

Maritime Administration

FARRELL LINES INC.

Notice of Application

Notice is hereby given that Farrell Lines Incorporated has filed application for waiver under section 804 of the Merchant Marine Act, 1936, as amended, to act as agent, including solicitation and booking of cargo and passengers moving to and from West Africa at the United States ports of New York, Philadelphia, and Baltimore and such other U.S. ports to which they may extend their present agency arrangements, and at Monrovia, Liberia, for the Nigerian National Line, Ltd., under the terms and provisions of a proposed agency arrangement dated March 13, 1964.

Any person, firm or corporation having an interest in such application who desires to offer views and comments thereon for consideration by the Maritime Administrator should submit same in writing, in triplicate, to the Secretary, Maritime Administration, Washington, D.C., by close of business June 19, 1964. The Maritime Administrator will consider these views and comments and take such action with respect thereto as he may deem appropriate.

Dated: June 11, 1964.

By order of the Maritime Administrator.

James S. Dawson, Jr.,
Secretary.

[F.R. Doc. 64-5938; Filed, June 12, 1964; 8:50 a.m.]

Office of the Secretary

[Dept. Order No. 152 (Rev.), Amdt. 1; Organization and Function Supp. (Rev.)]

BUSINESS AND DEFENSE SERVICES ADMINISTRATION

Organization and Assignment of Functions

This material amends the material appearing at 29 F.R. 5409–5410 of April 22, 1964.

Section 2–6 of the Organization and Function Supplement dated April 2, 1964 to Department Order No. 152 (Revised) is hereby amended as follows:

SEC. 2. *Organization.* The Business and Defense Services Administration shall consist of the following organization units:

* * * * *

6. Office of Chemicals and Consumer Products:

Chemicals and Allied Products Division.
Consumer Durables Division.
Food Industries Division.
Rubber, Leather and Allied Products Division.

Effective date. May 27, 1964.

Herbert W. Klotz,
Assistant Secretary for Administration.

[F.R. Doc. 64-5863; Filed, June 12, 1964; 8:47 a.m.]

DEPARTMENT OF HEALTH, EDUCATION, AND WELFARE

Food and Drug Administration

SYRACUSE UNIVERSITY RESEARCH CORP.

Notice of Filing of Petition Regarding Food Additive Toluene

Pursuant to the provisions of the Federal Food, Drug, and Cosmetic Act (sec. 409(b)(5), 72 Stat. 1786; 21 U.S.C. 348-(b)(5)), notice is given that a petition (FAP 1406) has been filed by Syracuse University Research Corporation, 1075 Comstock Avenue, Syracuse 10, New York, proposing the issuance of a regulation to provide for the safe use of toluene in the manufacture of foamed polystyrene intended for use in contact with food, if the finished foamed polystyrene does not contain more than 0.35 percent by weight of toluene.

Dated: June 8, 1964.

MALCOLM R. STEPHENS,
Assistant Commissioner
for Regulations.

[F.R. Doc. 64-5886; Filed, June 12, 1964; 8:48 a.m.]

ECONOMICS LABORATORY, INC.

Notice of Filing of Petition Regarding Food Additive Sanitizing Solutions

Pursuant to the provisions of the Federal Food, Drug, and Cosmetic Act (sec. 409(b)(5), 72 Stat. 1786; 21 U.S.C. 348 (b)(5)), notice is given that a petition (FAP 1375) has been filed by Economics Laboratory, Inc., Guardian Building, St. Paul, Minnesota, 55101, proposing an amendment to § 121.2547 *Sanitizing solutions* to provide for the safe use of a sanitizing solution consisting in part of iodine, ethylene glycol monobutyl ether, butoxy monoether of mixed (ethylene-propylene) polyalkylene glycol having a cloud-point of 90° C.–100° C. in 0.5 percent aqueous solution, and diethylene glycol monoethyl ether, in addition to components generally recognized as safe for the intended use.

Dated: June 8, 1964.

MALCOLM R. STEPHENS,
Assistant Commissioner
for Regulations.

[R.F. Doc. 64-5845; Filed, June 12, 1964; 8:45 a.m.]

CIVIL AERONAUTICS BOARD

[Docket Nos. 12307, 14228; Order E-20909]

CORDOVA AIRLINES, INC.

Order Amending Previous Exemption Orders

Adopted by the Civil Aeronautics Board at its office in Washington, D.C., on the 9th day of June 1964.

Application of Cordova Airlines, Inc., for amendment of exemption authority granted pursuant to Order E-17234, July 27, 1961, Docket 12307; application of Cordova Airlines, Inc., for amendment of exemption authority granted pursuant to Order E-19478, April 9, 1963, Docket 14228.

By application filed April 1, 1964, Cordova Airlines, Inc. (Cordova) requests that its route exemption authority to provide scheduled air transportation of persons and property between the terminal point Anchorage and the intermediate points Soldotna, Kasilof, Ninilchik, Seldovia, and the terminal point Port Graham, all in Alaska, which was granted pursuant to Order E-17234, July 27, 1961, be amended so as to make the route eligible for subsidy pursuant to section 406 of the Federal Aviation Act of 1958, as amended (Act), and to permit the use of aircraft exceeding 12,500 pounds gross take-off weight.[1] Cordova also requests that Order E-19478, April 9, 1963, which by exemption authorizes Cordova to provide scheduled air transportation of persons, property and mail between the terminal point Homer and the terminal point Port Graham, via the intermediate points Halibut Cove, Red Mountain, Seldovia, and English Bay, all in Alaska, be amended so as to make the route eligible for subsidy pursuant to section 406 of the Act, and to permit the carrier to conduct charter and contract operations to and from the points named on this route as if Cordova were authorized to serve the route by a certificate of public convenience and necessity.[2] The exemption authority granted by both orders remains effective until 90 days after final determination on Cordova's application for certificate authority on these routes.[3]

In support of its application for amendment of the above orders, Cordova alleges, inter alia, that the Alaskan earthquake has created an unparalleled transportation emergency; that, with the exception of scheduled service to Homer and Kenai, Cordova provides the only scheduled air transportation service to the Kenai Peninsula of Alaska; that the surface roads and bridges have been destroyed or rendered unusable by the earthquake and that water transportation has been severely reduced by the loss of ships and dock facilities caused by tidal wave damage resulting from the earthquake. Cordova states that the points in question have always been isolated but that the earthquake has increased the isolation and that air transportation is the only available transportation service remaining. It further alleges that, because the earthquake has caused a chaotic financial situation in Alaska, there is no way of estimating the costs of providing services under present conditions. For this reason, and because Cordova cannot and should not be expected to undertake large-scale emergency operations entirely at its own risk, the applicant requests that the points served pursuant to the two Board orders granting exemption authority be made eligible for subsidy. Cordova contends that unless immediate subsidy eligibility is granted it may be forced to terminate the operation.

Cordova states that its operations on the Kenai route show that it has performed an important and valuable service to isolated communities on the Kenai Peninsula, and that the substantial number of passengers and volume of freight transported constitute a major portion of Cordova's operations. According to the applicant's traffic figures there has been a substantial need for scheduled air service between the points authorized in the exemption orders and Cordova has been satisfying this need. Moreover, Cordova alleges, this need has been greatly increased because of the earthquake.

In support of the amendment requested to Order E-19478 to permit the operation of charter and contract services, Cordova alleges that the air taxi operators on the Kenai Peninsula do not have adequate equipment to perform necessary charter and contract services. The applicant alleges that it has received a large number of requests for charter services, particularly at Homer, to over-water points; and that the air taxi operators in the market do not have aircraft equipped with pontoons for landing on water. For this reason Cordova states that they cannot serve many of the points that are now requesting charter services and that Cordova is ready, willing and able to employ twin-engine amphibious Widgeons to provide the service requested. The applicant also requests that it be permitted to use aircraft having a gross take-off weight in excess of 12,500 pounds for the services provided pursuant to Order E-17234 in order that it may be able to use the most suitable aircraft in serving such points.

Communications in support of Cordova's applications have been filed with the Board by the Soldotna Chamber of Commerce, the Soldotna City Council, the Homer City Council, the Ninilchik Chamber of Commerce, the Ninilchik General Store and Garage, Ursin Sea Foods of Anchorage, and Mr. Lou Collier, a Seldovia City Councilman.

Answers and communications in opposition to the applications have been filed by the Alaskan Independent Air Carriers Association and various noncertificated operators, including Homer Air Service, Sky Van Airways, and Cook Inlet Aviation, Inc. (Cook Inlet).[4] The principal argument advanced by these parties is that the air taxi operators and independent air carriers of Alaska are ready, willing and able to provide the proposed service without subsidy and that the grant of subsidy to Cordova for the exemption routes in question would adversely affect the well-being of air taxi operators, as well as independent air carriers, serving the Kenai Peninsula. They also maintain that the air transportation needs of the area are being adequately served at this time by the air taxi operators. Cook Inlet alleges that the Kenai Peninsula area is no more isolated now than it was prior to the earthquake. It states that it is not aware of a serious deterioration of surface transportation and that water transportation did not deteriorate at all. Furthermore, Cook Inlet alleges that Cordova's financial results in serving the Kenai area do not indicate that subsidy is required. It disputes Cordova's contention that certain points in the area can only be served by amphibious aircraft.

---

[1] Ordering paragraph 1 of Order E-17234 restricts Cordova to the use of aircraft having a maximum gross take-off weight of 12,500 pounds. Order E-19478 extends the authority granted by Order E-17234 until 90 days after final determination of Cordova's application in Docket 14389.

[2] In Order E-19893, August 9, 1963, we made clear that Order E-19478 did not contemplate that Cordova could undertake charter, contract or special services.

[3] Ordering paragraphs 3 and 4 of Order E-19478; Cordova has applied for such authority in Docket 14389.

[4] Homer Air Service and Cook Inlet Aviation, Inc., are Alaskan air taxi operators; Sky Van Airways is a Part 45 air carrier based at Seattle, Washington.

In Order E-17234, July 27, 1961, we denied subsidy eligibility to Cordova for the exemption route authorization granted therein. This departure from our usual practice of permitting both the certificate and exemption routes of an air carrier to be eligible for subsidy resulted from the fact that Cordova had acquired the exemption route here in question from an air carrier which was not eligible for, and did not receive, subsidy for similar operations. In that order we stated that it would be "unsound policy for the Board, in the absence of compelling and unusual circumstances, to convert an authorization awarded on a nonsubsidy basis to a subsidy basis without a full evidentiary hearing and thus without any real opportunity to ascertain the extent of the obligation to which the Government might be committed." The companion route exemption authority granted by Order E-19478, April 9, 1963, was also made ineligible for subsidy.

In our judgment, the Alaska earthquake has created "compelling and unusual circumstances" warranting the grant of immediate relief to the carrier. Cordova's traffic data[5] indicate that it is providing needed scheduled air transportation services in the Kenai area. The applicant provides the only scheduled air service to Soldotna, Kasilof, Ninilchik, Seldovia, Port Graham, Red Mountain, Halibut Cove and English Bay. Cordova alleges that the Alaska earthquake has caused the area to become more isolated and therefore in greater need of air transportation; and that "unless immediate subsidy eligibility is granted Cordova may be forced to terminate this service." Cordova's allegations with respect to the need for services are supported by various civic interests in the area. We recognize that various competing carriers deny that the Kenai area has become isolated because of the earthquake and contest generally the need for Cordova's services to the peninsula. A definitive resolution of all of the contested issues may have to await our final determination after a hearing upon Cordova's certificate application. However, on the basis of the pleadings before us and taking judicial notice of the widespread disruption and dislocations caused by the Alaska earthquake, as well as Cordova's financial distress, we find for the purposes of the instant application that a cessation of Cordova's services to the peninsula at the present time would be adverse to the public interest. In view of the danger that Cordova will not be able to continue its present services without financial assistance, we will provide for subsidy eligibility for operations over the exemption routes in question.[6]

For the same reasons, and in order to permit Cordova to operate with greater flexibility we will also amend Order E-19478, April 9, 1963, to authorize Cordova to conduct charter trips and special services for the route granted by exemption therein. However, in order to protect the air taxi operators in this market, we will not permit Cordova to conduct such charter trips and special services with aircraft of less than 12,500 pounds maximum gross take-off weight. Cordova shall comply with section 292.8 as if it served the said route pursuant to a certificate of public convenience and necessity. Similarly, we will amend Order E-17234, July 27, 1961, to permit the use of aircraft of more than 12,500 pounds maximum gross take-off weight for the routes granted by exemption therein. These amendments shall also have a duration of one year from the date of service of this order.

We note that Cordova has held the basic exemption authority in question since 1961. Clearly, it would be undesirable to permit Cordova to operate these routes indefinitely on an exemption basis. This is particularly true where, as here, various parties have long contended that there is no need for Cordova's service and their allegations have never been exposed to the hearing process. Consequently, we will, in the near future, institute a proceeding to determine whether any air carrier should receive a certificate of public convenience and necessity to operate to the points now being served by Cordova by exemption, and whether such routes should be made eligible for subsidy.[7]

In view of the foregoing, we find that the enforcement of the provisions of section 401 insofar as they would otherwise prevent Cordova from engaging in the air transportation authorized herein, would be an undue burden on the carrier by reason of the unusual circumstances affecting its operations, and would not be in the public interest.

Accordingly, it is ordered:

1. That notwithstanding ordering paragraph 1 of Order E-17234, July 27, 1961, Cordova may, for the operations authorized by such order, utilize aircraft in excess of 12,500 pounds gross take-off weight for a period of one year from the date of service of this order;

2. That notwithstanding ordering paragraphs 1 and 2 of Order E-17234, July 27, 1961, as extended by Order E-19478, the operations authorized by the said order shall be eligible for Federal subsidy under section 406 of the Act for a period of one year from the date of service of this order;

3. That notwithstanding ordering paragraphs 1 and 2 of Order E-19478, April 9, 1963, the operations authorized by the said order shall be eligible for Federal subsidy under section 406 of the Act for a period of one year from the date of service of this order;

4. That notwithstanding Order E-19478, April 9, 1963, and Order E-19893, August 9, 1963, Cordova may operate charter trips and special services as if the route were operated pursuant to a certificate of public convenience and necessity for a period of one year from the date of service of this order; and that, as so operated, Cordova shall not utilize aircraft of a maximum gross take-off weight of less than 12,500 pounds and shall comply with the requirements of section 292.8 of the Board's Economic Regulations;

5. That this order may be amended or revoked at any time in the discretion of the Board without hearing; and

6. That a copy of this order be published in the FEDERAL REGISTER.

By the Civil Aeronautics Board.

[SEAL] HAROLD R. SANDERSON,
Secretary.

[F.R. Doc. 64-5898; Filed, June 12, 1964; 8:49 a.m.]

FEDERAL AVIATION AGENCY

[OE Docket 64-SW-3]

SOUTHWEST REPUBLIC CORP.

Determination of No Hazard to Air Navigation

The Federal Aviation Agency circularized the following proposal for aeronautical comment and has conducted an aeronautical study (SW-OE-6290) to determine its effect upon the safe and efficient utilization of the navigable airspace.

The Southwest Republic Corporation, Austin, Texas, proposed to construct a television antenna structure near Austin, Texas, at latitude 30°19′33″ north, longitude 97°47′58″ west. The overall height of the structure would be 2049 feet above mean sea level (1199 feet above ground).

The structure would exceed the standards for determining hazards to air navigation as defined in § 77.23(a)(2) of the Federal Aviation Regulations by 999 feet since it would be more than 200 feet above ground within the boundaries of an airway.

The aeronautical study disclosed that the structure would be located approximately 1.2 miles from an existing structure of equal height. It would have no greater effect upon aeronautical procedures or operations than the existing structure which is the controlling obstruction for aeronautical operations in this area.

The collocation of these structures in the antenna farm area concept is consistent with the Agency's policy as expressed in § 77.81 of the FAR. Although this is not a proposal for an antenna farm area this arrangement minimizes the effect of structures of this type upon aeronautical operations.

Based on the aeronautical study, it is the finding of the Agency that the proposed structure would have no substantial adverse effect upon aeronautical operations, procedures or minimum flight altitudes.

Therefore, pursuant to the authority delegated to me by the Administrator (§ 77.37 [New]), it is found that the proposed structure would have no substantial adverse effect upon the safe and efficient utilization of navigable airspace and it is hereby determined that the proposed structure would not be a hazard to air navigation provided that it is obstruction marked and lighted in accordance with Agency standards.

---

[5] Cordova alleges that it transported 7,763 passengers and 200,741 pounds of freight between Anchorage and Seldovia for the year ended July 31, 1963; and 1,195 passengers between Homer and Seldovia in May-July 1963.

[6] We do not of course make any final determination at this time as to the amount of Cordova's need, if any, for subsidy to operate the routes in question.

[7] This proceeding will include Cordova's route application in Docket 14389.

This determination is effective and will become final 30 days after the date of issuance unless an appeal is filed under § 77.39 [New] (27 F.R. 10352). If the appeal is denied, the determination will then become final as of the date of the denial or 30 days after the issuance of the determination, whichever is later. Unless otherwise revised or terminated, a final determination hereunder will expire 18 months after its effective date or upon earlier abandonment of the construction proposal (§77.41 [New]).

Issued in Washington, D.C., on June 5, 1964.

RALPH H. FLETCHER,
Acting Chief,
Obstruction Evaluation Branch.

[F.R. Doc. 64-5861; Filed, June 12, 1964; 8:46 a.m.]

[OE Docket 64-SO-4]

WKY TELEVISION SYSTEM, INC.

Determination of Hazard to Air Navigation

The Federal Aviation Agency has circularized the following proposal for aeronautical comment and has conducted a study (SO-OE-3185) to determine its effect upon the safe and efficient utilization of navigable airspace.

WKY Television System, Inc., WTVT-TV, Tampa, Florida, proposes to construct a television antenna structure approximately 4.3 miles northeast of Balm, Florida, at latitude 27°49′09″ north, longitude 82°14′26″ west. The overall height of the proposed structure would be 1449 feet above mean sea level (1363 feet above ground).

A similar proposal for a tower 1649 feet above mean sea level (1563 feet above ground) at the above site was considered in Aeronautical Study No. SO-OE-1969. As a result of the study, a determination of hazard was issued in OE Docket No. 63-SO-8 on August 23, 1963.

The proposed structure would be located approximately 1.9 miles southeast of an existing television antenna structure having an overall height of 1135 feet above mean sea level, 15.4 miles east of MacDill Air Force Base, and 18.5 miles southwest of the Lakeland, Florida, Airport.

It would also be located within five miles of two approved off-airway air carrier routes and would exceed the standards for determining hazards to air navigation as defined in § 77.23(a)(3) of the Federal Aviation Regulations as applied to these routes.

The proposed structure would require the following changes in currently prescribed minimum flight altitudes in order to provide minimum obstruction clearance altitudes in accordance with Agency standards:

1. It would require an increase from 2100 feet to 2400 feet in the minimum en route altitude on approved off-airway direct route between the Tampa, Florida nondirectional radio beacon and the West Palm Beach, Florida, nondirection radio beacon.

2. It would require an increase from 1600 feet to 2400 feet in the minimum en route altitude on approved off-airway direct route between the Sarasota, Florida, VOR and the Lakeland, Florida, VOR.

3. It would require an increase from 1600 feet to 1900 feet in the procedure turn altitude for standard instrument approach procedure AL-939-VOR-RWY-4 for Lakeland, Florida.

4. It would require an increase from 1500 feet to 1700 feet in the procedure turn altitude for standard instrument approach procedure AL-416-ADF-2 for Tampa International Airport.

5. It would generally require an increase from 1500 feet to 2400 feet in the minimum radar vectoring altitude within three miles of the site and from 1500 to 1900 feet within three to five miles of the site. A minimum radar vectoring altitude of 2100 feet is presently required just northwest of the site because of the existing 1135-foot tower.

The above changes in IFR operations which would be required to accommodate the proposed structure would not be substantial in nature, since infrequent use is made of the altitudes affected.

The aeronautical study conducted under Study No. SO-OE-1969 as well as the current study disclosed that there is a heavy volume of flight operations conducted in the Tampa/St. Petersburg terminal area. There are approximately 370,000 such operations each year of which the greater portion are itinerant operations conducted by general aviation aircraft.

The MacDill A.F.B. Special Notice published in the Airman's Guide cautions airmen of heavy low level jet traffic operating between MacDill A.F.B. and the Avon Park Bomb and Gunnery Range, R-2901. Although the Air Force aircraft operate at altitudes which would not be affected by the proposed structure, the volume of traffic involved would tend to confine general aviation VFR activity to the lower altitudes.

As disclosed on the earlier determination, the low, flat character of the terrain in this area and on the Florida peninsula favors low altitude flight operations. The low winter stratus cloud conditions and frequent thunderstorm and broken to overcast cumulus cloud formations in the nonwinter months further restrict such flights to low altitudes.

Based upon the aeronautical study, it is the finding of the Agency that the proposed structure would create an unsafe obstruction to low altitude VFR operations in the Tampa/St. Petersburg terminal area.

Therefore, pursuant to the authority delegated to me by the Administrator (§ 77.37 [New]), it is found that the proposed structure would have a substantial adverse effect upon the safe and efficient utilization of navigable airspace, and it is hereby determined that the proposed structure would be a hazard to air navigation.

This determination is effective and will become final 30 days after the date of issuance unless an appeal is filed under § 77.39 [New] (27 F.R. 10352). If the appeal is denied, the determination will then become final as of the date of the denial or 30 days after the issuance of the determination, whichever is later.

Issued in Washington, D.C., on June 4, 1964.

RALPH H. FLETCHER,
Acting Chief,
Obstruction Evaluation Branch.

[F.R. Doc. 64-5862; Filed, June 12, 1964; 8:47 a.m.]

FEDERAL COMMUNICATIONS COMMISSION

[Docket Nos. 15312-15315; FCC 64M-515]

ALL-FLORIDA COMMUNICATIONS CO. ET AL.

Order Continuing Hearing

In re applications of Alan H. Rosenson, d/b as All-Florida Communications Company, Docket No. 15312, File No. 2437-C2-MP-63, for modification of a construction permit for station KIN645 in the Domestic Public Land Mobile Radio Service at Miami, Florida; Benjamin Cutler, Docket No. 15313, File No. 3320-C2-P-63, for a construction permit in the Domestic Public Land Mobile Radio Service at Miami, Florida; Abe Schonfeld, d/b as Tel-Car, Docket No. 15314, File No. 3536-C2-P-63, for a construction permit for station KIB527 in the Domestic Public Land Mobile Radio Service at Miami, Florida; Professional Radio Service Corporation, Docket No. 15315, File No. 5080-C2-P-63, for a construction permit in the Domestic Public Land Mobile Radio Service at Miami, Florida.

It is ordered, This 8th day of June 1964, that a further hearing will be held in the above-captioned proceeding on June 30, 1964, at 2:30 p.m. in the Commission's offices, Washington, D.C.

Released: June 9, 1964.

FEDERAL COMMUNICATIONS COMMISSION,
[SEAL] BEN F. WAPLE,
Secretary.

[F.R. Doc. 64-5887; Filed, June 12, 1964; 8:49 a.m.]

[Docket No. 14832; FCC 64M-522]

BIGBEE BROADCASTING CO.

Order Continuing Hearing

In re application of Paul D. Nichols, William C. Reid, and Houston L. Pearce d/b as Bigbee Broadcasting Co., Demopolis, Alabama, Docket No. 14832, File No. BP-13976, for construction permit.

Upon oral request of counsel for Demopolis Broadcasting Company, Inc., respondent in the above-entitled matter, and with the consent of the other parties: *It is ordered,* This 9th day of June 1964, that the prehearing conference presently scheduled to be held on June 11, 1964, at 2:00 p.m., be, and the same is, hereby continued to June 19, 1964, at 2:00 p.m.

Released: June 10, 1964.

Federal Communications
Commission,
[SEAL] Ben F. Waple,
Secretary.

[F.R. Doc. 64-5888; Filed, June 12, 1964; 8:49 a.m.]

[Docket Nos. 15303, 15304; FCC 64M-523]

CASCADE BROADCASTING CO. AND SUNSET BROADCASTING CO. (KNDX-FM)

Order Continuing Hearing

In re applications of Cascade Broadcasting Company, Yakima, Washington, Docket No. 15303, File No. BPH-4072; David Zander Pugsley tr/as Sunset Broadcasting Company (KNDX-FM) Yakima, Washington, Docket No. 15304, File No. BPH-4180; for construction permits.

The Hearing Examiner having under consideration the desirability of postponing the date for commencement of hearing;

It appearing, That requests for rule making have been filed which may obviate the necessity of a hearing so that it would be futile to proceed with a hearing on the currently scheduled date of June 11;

It is ordered, This 10th day of June 1964, that the commencement of hearing is continued from June 11, 1964, to July 16, 1964.

Released: June 10, 1964.

Federal Communications
Commission,
[SEAL] Ben F. Waple,
Secretary.

[F.R. Doc. 64-5889; Filed, June 12, 1964; 8:49 a.m.]

[Docket Nos. 12865, 12866; FCC 64M-516]

CHRONICLE PUBLISHING CO. (KRON-TV) AND AMERICAN BROADCASTING-PARAMOUNT THEATRES, INC. (KGO-TV)

Memorandum Opinion and Order Continuing Prehearing Conference

In re applications of Chronicle Publishing Company (KRON-TV), San Francisco, California, Docket No. 12865, File No. BPCT-2168; American Broadcasting-Paramount Theatres, Inc. (KGO-TV), San Francisco, California, Docket No. 12866, File No. BPCT-2401; for construction permits.

1. The Federal Aviation Agency has recently entered orders in two of its proceedings relating to the applicants herein[1] which may conceivably have some bearing on certain aspects of the instant proceeding.

2. It is deemed appropriate that in light of the Federal Aviation Agency's decisions that time should be accorded the parties herein to study said decisions prior to a further prehearing conference.

3. Therefore, the date now scheduled for the prehearing conference should be deferred for a reasonable period of time.

Accordingly, it is ordered, This 8th day of June 1964, that the prehearing conference herein now scheduled for June 16, 1964, is cancelled; and, that a further prehearing conference is hereby scheduled for June 29, 1964, 10:00 a.m., in the Commission's Offices, Washington, D.C.

Released: June 9, 1964.

Federal Communications
Commission,
[SEAL] Ben F. Waple,
Secretary.

[F.R. Doc. 64-5890; Filed, June 12, 1964; 8:49 a.m.]

[Docket Nos. 15485, 15486; FCC 64M-525]

DIRIGO BROADCASTING, INC., AND DOWNEAST TELEVISION, INC.

Order Scheduling Prehearing Conference

In re applications of Dirigo Broadcasting, Inc., Bangor, Maine, Docket No. 15485, File No. BPCT-2911; Downeast Television, Inc., Bangor, Maine, Docket No. 15486, File No. BPCT-2952; for a construction permit for new television broadcast station.

On the Examiner's own motion: *It is ordered,* This 9th day of June 1964, that the prehearing conference presently scheduled in the above-entitled matter for June 17, 1964, at 10:00 a.m., be, and the same is, hereby rescheduled for 9:00 a.m. on the same date.

Released: June 10, 1964.

Federal Communications
Commission,
[SEAL] Ben F. Waple,
Secretary.

[F.R. Doc. 64-5891; Filed, June 12, 1964; 8:49 a.m.]

[Docket No. 15496; FCC 64M-524]

HI-DESERT MICROWAVE, INC.

Order Scheduling Hearing

In re applications of Hi-Desert Microwave, Inc., Docket No. 15496, File Nos. 3740/3741/3742/3743-C1-P-63, 8/9-C1-R-63, for renewal of facilities and for construction permits to establish new facilities in the Domestic Public Point-to-Point Microwave Radio Service.

It is ordered, This 8th day of June 1964, that Chester F. Naumowicz, Jr., shall serve as the presiding officer in the above-entitled proceeding; that the hearings therein shall commence at 10:00 a.m. on July 27, 1964; and that a prehearing conference shall be convened at 9:00 a.m. on July 7, 1964: *and it is further ordered,* That all proceedings shall be held in the offices of the Commission, Washington, D.C.

Released: June 10, 1964.

Federal Communications
Commission,
[SEAL] Ben F. Waple,
Secretary.

[F.R. Doc. 64-5892; Filed, June 12, 1964; 8:49 a.m.]

[Docket No. 14611; FCC 64M-517]

PROGRESS BROADCASTING CORP. (WHOM)

Memorandum Opinion and Order Continuing Hearing

In re application of Progress Broadcasting Corporation (WHOM), New York, New York, Docket No. 14611, File No. BP-13915; for construction permit.

1. The applicant filed on May 1, 1964, its petition to postpone date for exchange of exhibits and commencement of hearing. It also requested oral argument on said petition.

2. Oral argument was heard on June 8, 1964, after having been continued because of certain circumstances; and, as a result thereof, the petition should be dismissed as moot.

3. On May 11, 1964, the Commission's Broadcast Bureau filed its petition to dismiss the Progress application for failure to prosecute. Opposition to the petition to dismiss was filed by Progress on May 21, 1964.

4. At the oral argument referred to above, counsel for all parties were in accord that this matter should be held in abeyance without setting a hearing date pending final disposition by the Review Board of said petition to dismiss.

5. It is established that good cause exists why the hearing herein should be continued without date.

Accordingly, it is ordered, This 9th day of June 1964, that the applicant's petition to postpone date for exchange of exhibits and commencement of hearing be and the same is dismissed as moot.

It is further ordered, That because of the pendency of the Broadcast Bureau's petition to dismiss for failure to prosecute, the hearing herein is continued without date.

Released: June 9, 1964.

Federal Communications
Commission,
[SEAL] Ben F. Waple,
Secretary.

[F.R. Doc. 64-5893; Filed, June 12, 1964; 8:49 a.m.]

[Docket Nos. 14909, 14910; FCC 64M-509]

SOUTHERN RADIO AND TELEVISION CO. AND ROBERT HECKSHER (WMYR)

Statement and Order After Prehearing Conference

In re application of Southern Radio and Television Co. Lehigh Acres, Florida,

---

[1] American Broadcasting-Paramount) Theatres, Inc., KGO-TV, 29 F.R. 7296; Chronicle Publishing Company (KRON-TV), 29 F.R. 7298.

Docket No. 14909, File No. BP-14297; Robert Hecksher (WMYR), Fort Myers, Florida, Docket No. 14910, File No. BP-14378; for construction permit.

At a prehearing conference on June 5, 1964, on the remand, among other things procedural dates were scheduled as follows:

Applicant Southern Radio to furnish its written direct case by July 20, 1964.

Receipt of notification of witnesses desired for cross-examination by July 27, 1964.

Further prehearing conference Wednesday, July 29, 1964, at 9 a.m.

Hearing Wednesday, Sept. 9, 1964, at 10 a.m.

It is understood that if indicated and the schedules of counsel and the Hearing Examiner permit, the conference and hearing dates may be canceled or accelerated.

So ordered, This 8th day of June 1964.

Released: June 8, 1964.

FEDERAL COMMUNICATIONS
COMMISSION,
[SEAL] BEN F. WAPLE,
Secretary.

[F.R. Doc. 64-5894; Filed, June 12, 1964; 8:49 a.m.]

[Docket Nos. 15449, 15450; FCC 64M-518]

SPRINGFIELD TELECASTING CO. AND MIDWEST TELEVISION, INC.

Order Following Prehearing Conference

In re applications of Springfield Telecasting Co., Springfield, Illinois, Docket No. 15449, File No. BPCT-2838; Midwest Television, Inc., Springfield, Illinois, Docket No. 15450, File No. BPCT-2846; for construction permits for new television broadcast stations.

A prehearing conference having been held on June 8, 1964, and it appearing that certain agreements were reached therein which should be formalized by order;

It is ordered, This 8th day of June 1964, that:

(1) Proposed exhibits of Springfield Telecasting Company pertaining to Issues 1 and 3 shall be exchanged by July 6, 1964;

(2) Notification as to those of applicant Springfield's witnesses required for cross-examination at the hearing in connection with Issues 1 and 3 shall be given to its counsel by July 16, 1964; and

(3) The hearing heretofore scheduled to commence on July 15, 1964, is postponed to July 21, 1964, at 10:00 a.m., in the offices of the Commission at Washington, D.C.

Released: June 9, 1964.

FEDERAL COMMUNICATIONS
COMMISSION,
[SEAL] BEN F. WAPLE,
Secretary.

[F.R. Doc. 64-5895; Filed, June 12, 1964; 8:49 a.m.]

[Docket Nos. 15434, 15435; FCC 64M-521]

WENY, INC., AND ELMIRA HEIGHTS-HORSEHEADS BROADCASTING CO.

Order Continuing Hearing

In re applications of WENY, Inc., Elmira, New York, Docket No. 15434, File No. BPH-4259; Frank P. Saia, Emmagene Swezey Saia, and Anthony P. Saia, d/b as Elmira Heights-Horseheads Broadcasting Company, Elmira, New York, Docket No. 15435, File No. BPH-4261; for construction permits.

To formalize the agreements and rulings made on the record at a prehearing conference held on June 9, 1964, in the above-entitled matter concerning the future conduct of this proceeding;

It is ordered, This 9th day of June 1964, that:

Exchange of exhibits is scheduled for July 28, 1964;

Notification of Witnesses is scheduled for September 1, 1964; and

Hearing presently scheduled for July 13, 1964, is rescheduled for September 9, 1964.

Released: June 10, 1964.

FEDERAL COMMUNICATIONS
COMMISSION,
[SEAL] BEN F. WAPLE,
Secretary.

[F.R. Doc. 64-5896; Filed, June 12, 1964; 8:49 a.m.]

[Docket No. 15373; FCC 64R-320]

WHITNEY TELEPHONE ANSWERING SERVICE

Memorandum Opinion and Order Amending Issues

In re application of Helen J. Monaco, d/b as Whitney Telephone Answering Service, Docket No. 15373, File No. 4028-C2-P-63, for a construction permit to establish new facilities in the Domestic Public Land Mobile Radio Service at Hamden, Connecticut.

1. Connecticut Radio Foundation, Inc. (Connecticut Radio), licensee of Station KCC479, New Haven, Connecticut, and party to the above-entitled proceeding, requests an enlargement of issues to inquire into whether the applicant's proposed station would interfere with the operation of Station KED349, Somers, New York.[1] Connecticut Radio contends that, since the applicant proposes to use the same base station frequency (152.12 mcs.) as that utilized by KED349, the applicant's proposed station would cause interference to KED349 within its 37 dbu contour. The allegation is supported by an affidavit of Connecticut Radio's engineering consultant. Petitioner urges that the burden of proof should be placed upon the applicant.

2. In opposition, Helen J. Monaco (Monaco) argues that the petition is defective because it is not supported by an affidavit of a person, or persons, having personal knowledge of the factual allegations therein. Monaco alleges that, although the engineer's statement purports to rely upon facts stated in the application and in the station file of Station KED349, the facts relied upon are in error in a number of respects and other material and relevant facts contained in such files are ignored, and that, these errors, coupled with a misapplication of the Boese Report,[2] result in the erroneous conclusion that the proposed Monaco station near Hamden, Connecticut, will cause harmful co-channel interference within the 37 dbu contour of Station KED349 at Somers, New York. Monaco further alleges that neither the coordinates of the proposed station nor those for KED349 shown in the engineering statement are in accordance with the coordinates as shown by the Commission files (however, Monaco does not furnish the correct coordinates); that the airline distance as calculated by Connecticut Radio is erroneous; and that while the application shows the transmission line loss of the Monaco station as 1.6 db, Connecticut Radio calculates the line loss as 1.3 db. Monaco contends that profile and topographical data in the Station KED349 file shows that the effective base station antenna height for all directions toward the East, including the Monaco station, is substantially below the average terrain height; that at a distance of approximately nine to ten miles from KED349, the terrain is about 450 feet above the effective antenna height of KED349; that these ridges have the effect of sharply reducing the limits of the actual service area of KED349 to line-of-sight distances at the top of the nearest higher ridge and would prevent harmful co-channel interference from the Monaco station to the service area of KED349; and that thus the theoretical signals from the Monaco station, which ignore the terrain factors, have no real meaning or relevance with respect to the predicted interference.

3. In reply, Connecticut Radio contends that the preparation of its engineering affidavit is based on personal knowledge of information contained in the Commission's files; that its engineer is prepared to document his application of the Boese Report; that any difference in geographical coordinates is minimal; and that, by its petition, Connecticut Radio has remedied its previous defect of failing to make factual allegation of interference to Station KED349.

4. There are differences of opinion as to whether there will be interference between the station proposed by Monaco

---

[1] The Review Board has under consideration (a) a motion to enlarge issues filed April 2, 1964, by Connecticut Radio Foundation, Inc., New Haven, Conn.; (b) an opposition filed April 10, 1964, by Helen J. Monaco, d/b as Whitney Telephone Answering Service; and (c) a reply of Connecticut Radio Foundation, Inc., filed April 20, 1964. The Common Carrier Bureau filed no responsive pleading.

[2] T.R.R. Report No. 4.3.8.

herein and Station KED349 at Somers, New York, and the manner in which this determination has been made. The Review Board finds that the petitioner has made a threshold showing of interference. However, the positive determination of this question cannot be resolved by interlocutory pleadings and should be a matter to be considered after the introduction of evidence into the proceeding herein. The motion to enlarge issues will therefore be granted. As to the allegation by Monaco of lack of personal knowledge on the part of petitioner, it appears that such statement was made without complete examination of the information available to the public (and Connecticut Radio) in the Commission's files.

Accordingly, it is ordered, This 8th day of June 1964, That the Motion to Enlarge Issues filed April 2, 1964, by Connecticut Radio Foundation, Inc., is granted; and the Commission's Order of Designation (FCC 64-203), released March 13, 1964, is amended by the addition of the following issue:

To determine the nature and extent of any interference which would exist between the applicant's proposed facilities and the facilities of Station KED349, Somers, New York.

Released: June 10, 1964.

FEDERAL COMMUNICATIONS COMMISSION,
[SEAL] BEN F. WAPLE,
Secretary.

[F.R. Doc. 64-5897; Filed, June 12, 1964; 8:49 a.m.]

FEDERAL POWER COMMISSION

[Docket No. CP64-190]

ALABAMA-TENNESSEE NATURAL GAS CO.

Notice of Application

JUNE 8, 1964.

Take notice that on February 27, 1964, Alabama-Tennessee Natural Gas Company (Applicant), P.O. Box 918, Florence, Alabama, filed in Docket No. CP64-190 an application pursuant to section 7(c) of the Natural Gas Act for a certificate of public convenience and necessity authorizing the construction and operation of certain facilities and the sale and delivery of additional volumes of natural gas to existing customers, all as more fully set forth in the application on file with the Commission and open to public inspection.

Specifically, Applicant proposes to construct and operate approximately 6.5 miles of 12-inch pipeline paralleling and looping Applicant's existing mainline in Colbert County and approximately 2.2 miles of 12-inch pipeline paralleling and looping Applicant's existing Tennessee River crossing in Morgan and Limestone Counties, all in the State of Alabama. The proposed facilities will increase Applicant's daily system delivery capacity by 6,100 Mcf; Applicant's presently authorized daily delivery capacity is 99,680 Mcf.

The application shows the total estimated cost of the proposed facilities to be $621,000, which cost will be financed by funds from internal sources and short-term bank loans.

Applicant states that it will contract with Tennessee Gas Transmission Company for the gas supply necessary to meet the proposed increased sales.

This matter is one that should be disposed of as promptly as possible under the applicable rules and regulations and to that end:

Take further notice that preliminary staff analysis has indicated that there are no problems which would warrant a recommendation that the Commission designate this application for formal hearing before an examiner and that, pursuant to the authority contained in and subject to the jurisdiction conferred upon the Federal Power Commission by sections 7 and 15 of the Natural Gas Act, and the Commission's rules of practice and procedure, a hearing may be held without further notice before the Commission on this application provided no protest or petition to intervene is filed within the time required herein. Where a protest or petition for leave to intervene is timely filed, or where the Commission on its own motion believes that a formal hearing is required, further notice of such hearing will be duly given.

Under the procedure herein provided for, unless otherwise advised, it will be unnecessary for Applicant to appear or be represented at the hearing.

Protests or petitions to intervene may be filed with the Federal Power Commission, Washington, D.C., 20426, in accordance with the rules of practice and procedure (18 CFR 1.8 or 1.10) on or before July 1, 1964.

JOSEPH H. GUTRIDE,
Secretary.

[F.R. Doc. 64-5864; Filed, June 12, 1964; 8:47 a.m.]

[Project No. 2468]

CONSUMERS POWER CO.

Notice of Application for License

JUNE 8, 1964.

Public notice is hereby given that application has been filed under the Federal Power Act (16 U.S.C. 791a-825r) by Consumers Power Company (correspondence to: W. R. Boris, Secretary, Consumers Power Company, 212 West Michigan Avenue, Jackson, Michigan, 49201) for license for constructed Project No. 2468, known as the Croton Plant, located on Muskegon River, in the County of Newaygo, Michigan.

The project consists of: (1) A dam approximately 700 feet in length made up of a powerhouse, integral with the dam (length 147 feet), a gated spillway of hollow design (gross length about 242 feet), and left and right bank earth embankments (combined length about 300 feet) having a maximum height above the stream bed of approximately 51 feet; (2) a fish chute; (3) a 1,380-acre reservoir known as Croton Pond (about 2,600 acre-feet of usable storage from the drawdown usually limited to 2 feet—surface elevation 722.5); (4) a steel framed brick powerhouse on a concrete substructure containing two horizontal and two vertical units with a total capacity of 8,850 kw driven, respectively, by two horizontal turbines (8 runners) with a combined capacity of 8,000 hp (at 39.5 feet head) and two vertical turbines with a combined capacity of 3,460 hp (at 39 feet head); (5) a 7.2 kv circuit connection from the powerhouse to the low-side of the 7.2/46/138 kv transformer bank, a distance of about 700 feet; and appurtenant electrical and mechanical facilities.

Protests or petitions to intervene may be filed with the Federal Power Commission, Washington, D.C., 20426, in accordance with the rules of practice and procedure of the Commission (18 CFR 1.8 or 1.10). The last day upon which protests or petitions may be filed is July 28, 1964. The application is on file with the Commission for public inspection.

JOSEPH H. GUTRIDE,
Secretary.

[F.R. Doc. 64-5865; Filed, June 12, 1964; 8:47 a.m.]

[Docket No. RP64-42]

LONE STAR GAS CO.

Notice of Proposed Changes in Rates and Charges

JUNE 8, 1964.

Take notice that on June 1, 1964, Lone Star Gas Company (Lone Star), tendered for filing proposed changes in its FPC Gas Tariff, Original Volume No. 1, to be effective as of January 1, 1964.

The proposed changes reflect decreases in rates and charges in Lone Star's Rate Schedule PL-1, to Natural Gas Pipeline Company of America, Lone Star's sole jurisdictional customer, amounting to $9,399 annually, based upon sales for the 12-month period ended September 30, 1959, as adjusted. The reduced rates reflect the January 1, 1964, reductions in Federal income taxes for corporations from 52 percent to 50 percent. Lone Star requests that the notice requirements of the Commission's Regulations be waived so as to permit the proposed rate schedule to become effective as of January 1, 1964.

Copies of the proposed rates have been served by Lone Star upon its customer and interested state commissions. Comments may be filed on or before July 2, 1964.

JOSEPH H. GUTRIDE,
Secretary.

[F.R. Doc. 64-5866; Filed, June 12, 1964; 8:47 a.m.]

[Docket Nos. CP63-12, CP63-13]

MISSISSIPPI RIVER TRANSMISSION CORP. AND MISSISSIPPI RIVER FUEL CORP.

Notice of Further Postponement of Hearing

JUNE 8, 1964.

Notice is hereby given that the hearing in the above-designated matter now scheduled to resume on June 11, 1964, is hereby postponed until further notice.

By direction of the Commission.

JOSEPH H. GUTRIDE,
Secretary.

[F.R. Doc. 64-5867; Filed, June 12, 1964; 8:47 a.m.]

[Docket No. CP64-232]

NATURAL GAS PIPELINE COMPANY OF AMERICA

Notice of Application

JUNE 8, 1964.

Take notice that on April 9, 1964, Natural Gas Pipeline Company of America (Applicant), 122 South Michigan Avenue, Chicago, Illinois, 60603, filed an application at Docket No. CP64-232, pursuant to section 7(c) of the Natural Gas Act for a certificate of public convenience and necessity authorizing the construction and operation of a meter station and side tap connection on Applicant's existing transmission facilities in Rock Island County, Illinois, to enable it to sell and deliver natural gas to Illinois Power Company, an existing customer of Applicant, for resale and local distribution by Illinois Power Company, in the Villages of Reynolds and Sherrard and the unincorporated Community of Preemption, Illinois, all as more fully set forth in the application on file with the Commission and open to public inspection.

Applicant estimates the cost of the proposed facilities to be $9,800, which cost will be met from funds on hand.

Illinois Power Company proposes to serve the Villages of Reynolds and Sherrard and the unincorporated Community of Preemption, Illinois from the quantities of natural gas which Applicant has heretofore been authorized to sell and deliver to Illinois Power Company; and the sale and delivery by Applicant to Illinois Power Company will be made pursuant to, and in accordance with, Natural Gas Pipeline Company of America's FPC Gas Tariff.

This matter is one that should be disposed of as promptly as possible under the applicable rules and regulations and to that end:

Take further notice that, preliminary staff analysis has indicated that there are no problems which would warrant a recommendation that the Commission designate this application for formal hearing before an examiner and that, pursuant to the authority contained in and subject to the jurisdiction conferred upon the Federal Power Commission by sections 7 and 15 of the Natural Gas Act, and the Commission's rules of practice and procedure, a hearing may be held without further notice before the Commission on this application provided no protest or petition to intervene is filed within the time required. Where a protest or petition for leave to intervene is timely filed, or where the Commission on its own motion believes that a formal hearing is required, further notice of such hearing will be duly given.

Under the procedure herein provided for, unless otherwise advised, it will be unnecessary for Applicant to appear or be represented at the hearing.

Protests or petitions to intervene may be filed with the Federal Power Commission, Washington, D.C., 20426, in accordance with the rules of practice and procedure (18 CFR 1.8 or 1.10) on or before June 29, 1964.

JOSEPH H. GUTRIDE,
Secretary.

[F.R. Doc. 64-5868; Filed, June 12, 1964; 8:47 a.m.]

[Project No. 1764]

PANAMINT SPRINGS RESORT

Notice of Application for New License

JUNE 8, 1964.

Public notice is hereby given that application has been filed under the Federal Power Act (16 U.S.C. 791a-825r) by Panamint Springs Resort (correspondence to: Mr. Jack Vandelaar, Panamint Springs Resort, Lone Pine, California) for a new license for constructed Project No. 1764, located on the Darwin Wash. River at Lower Darwin Falls in Inyo County, California, and affecting lands of the United States.

The project consists of a small collecting flume and box located at Lower Darwin Falls, a steel pipe line about 4.5 miles long, a powerhouse having an installed capacity of 13 horsepower, and a short length of low voltage electric power line. About 10.9 acres of lands of the United States are occupied by the project.

Protests or petitions to intervene may be filed with the Federal Power Commission, Washington, D.C., 20426, in accordance with the rules of practice and procedure of the Commission (18 CFR 1.8 or 1.10). The last day upon which protests or petitions may be filed is August 3, 1964. The application is on file with the Commission for public inspection.

JOSEPH H. GUTRIDE,
Secretary.

[F.R. Doc. 64-5869; Filed, June 12, 1964; 8:47 a.m.]

[Docket No. G-20464 etc.]

TRANSWESTERN PIPELINE CO. ET AL.

Order Approving Continuance of Hearing in Excess of Thirty Days

JUNE 8, 1964.

Upon completion on May 27, 1964, of the direct case by all the applicants in this consolidated comparative proceeding the presiding examiner recessed the hearing to reconvene on July 21, 1964. Although the schedule established by the presiding examiner would require a recess in excess of thirty days, all parties concur that this schedule which provides for successive filings without any intervening hearing will ultimately result in actual curtailment of hearing time.

The Commission finds: It is appropriate in carrying out the provisions of the Natural Gas Act that the hearing in the above-entitled proceedings be continued to reconvene on July 21, 1964.

The Commission orders: The continuance of the hearing in the above-entitled proceedings to reconvene July 21, 1964, be and hereby is approved.

By the Commission.

[SEAL] JOSEPH H. GUTRIDE,
Secretary.

[F.R. Doc. 64-5870; Filed, June 12, 1964; 8:47 a.m.]

[Docket Nos. G-16477, CI62-600]

W. E. BAKKE ET AL.

Certificate of Public Convenience and Necessity; Notice of Succession; Gas Rate Schedule

JUNE 5, 1964.

W. E. Bakke (Operator), et al., Abel & Bancroft (Operator), et al., and Sohio Petroleum Company (Operator), et al., Docket No. G-16477[1]; Sohio Petroleum Company (Operator), et al. (successor to M. D. Abel, d.b.a. Abel & Bancroft (Operator), et al.), Docket No. CI62-600.

Order amending order issuing Certificate of Public Convenience and Necessity, accepting notice of succession and supplement to FPC Gas Rate Schedule for filing, redesignating FPC Gas Rate Schedule, making successor in interest co-respondent, redesignating proceeding, and accepting agreement and undertaking for filing.

On March 20, 1964, Sohio Petroleum Company (Operator), et al. (Applicant) filed in Docket No. CI62-600 an application pursuant to section 7(c) of the Natural Gas Act to amend the certificate of public convenience and necessity issued in said docket by substituting Applicant in lieu of M. D. Abel, d.b.a. Abel & Bancroft (Operator), et al., as certificate holder to reflect a succession of interest, all as more fully set forth in the application.

Applicant proposes to sell and deliver natural gas in interstate commerce to El Paso Natural Gas Company for resale from the Sprayberry Field Area, Reagan and Upton Counties, Texas, pursuant to a contract heretofore designated as the predecessor's FPC Gas Rate Schedule No. 1. The presently effective rate under said rate schedule is in effect subject to refund in Docket No. G-16477. On March 20, 1964, Applicant filed a motion to be made a co-respondent in said proceeding,[2] which motion includes an agreement and undertaking to refund any amount collected in excess of the amount to be found just and reasonable in said proceeding.

After due notice, no petition to intervene, notice of intervention, or protest to the granting of the application has been filed.

The Commission finds:

---

[1] Consolidated with Docket No. AR61-1, et al.

[2] The subject motion refers only to the predecessor's FPC Gas Rate Schedule No. 1. Changes in rate under other rate schedules of the predecessor are also involved in the proceeding in Docket No. G-16477.

(1) It is necessary and appropriate in carrying out the provisions of the Natural Gas Act and the public convenience and necessity require that the order issuing a certificate of public convenience and necessity in Docket No. CI62–600 to M. D. Abel, d.b.a. Abel & Bancroft (Operator) et al., should be amended as hereinafter ordered.

(2) The notice of succession and supplement to the related FPC gas rate schedule submitted by Applicant should be accepted for filing, and said rate schedule should be redesignated as that of Applicant.

(3) It is necessary and appropriate in carrying out the provisions of the Natural Gas Act that Applicant should be made a co-respondent in the rate proceeding in Docket No. G–16477, that said proceeding should be redesignated accordingly, and that Applicant's agreement and undertaking should be accepted for filing.

The Commission orders:

(A) The order issuing a certificate of public convenience and necessity in in Docket No. CI62–600 to M. D. Abel, d.b.a. Abel & Bancroft (Operator), et al., be and the same is hereby amended by substituting Applicant as certificate holder, and in all other respects said order shall remain in full force and effect.

(B) Applicant be and is hereby made a co-respondent in the pending rate proceeding in Docket No. G–16477 as of January 1, 1964, insofar as said proceeding involves sales made pursuant to a contract heretofore designated as M. D. Abel, d.b.a. Abel & Bancroft (Operator), et al., FPC Gas Rate Schedule No. 1 and herein redesignated as Applicant's FPC Gas Rate Schedule No. 91; said proceeding is hereby redesignated accordingly; and Applicant's agreement and undertaking to assure refund of any amount collected in excess of the amount to be found just and reasonable in said proceeding be and is hereby accepted for filing.

(C) Applicant shall comply with the refunding and reporting procedure required by the Natural Gas Act and § 154.102 of the regulations thereunder, and Applicant's agreement and undertaking filed in Docket No. G–16477 shall remain in full force and effect until discharged by the Commission.

(D) The notice of succession and supplement to the related FPC gas rate schedule are hereby accepted for filing, and said rate schedule is redesignated, all as follows:

New Designation		Former designation and description and date of instrument	Effective date
Sohio Petroleum Company (operator), et al.			
Rate schedule	Supplement		
91	----------	M. D. Abel, d.b.a. Abel & Bancroft (operator), et al., FPC Gas Rate Schedule No. 1.	
91	1–15	Supplement Nos. 1–15 to above.	
----------	----------	Notice of succession 3–19–64.	1–1–64
91	16	Assignment 1–1–64----	1–1–64

By the Commission.

[SEAL] JOSEPH H. GUTRIDE,
Secretary.

[F.R. Doc. 64–5877; Filed, June 12, 1964; 8:47 a.m.]

[Docket No. E–7044]

IOWA SOUTHERN UTILITIES

Notice of Application

JUNE 5, 1964.

Take notice that on May 20, 1964, an application was filed with the Federal Power Commission, pursuant to section 204 of the Federal Power Act by Iowa Southern Utilities Company (Applicant), a corporation organized under the laws of the State of Delaware and qualified to do business as a foreign corporation in the State of Iowa, seeking an order amending the Commission's order of July 1, 1963, authorizing the issuance of additional shares of Common Stock under Applicant's Employee Stock Purchase Plan.

By order issued August 27, 1962, Docket No. E–7044, the Commission authorized Applicant to issue 10,000 shares of Common Stock, $15 par, for issuance under an Employee Stock Purchase Plan. By order issued July 1, 1963, in Docket No. E–7103, the Commission authorized Applicant to issue up to 1,859,628.2 shares of Common Stock, $10 par to accomplish a two for one split in Applicant's Common Stock and a reduction in the par value from $15 to $10 per share. In its application for the two for one split, Applicant did not request any increase in the number of shares for issuance under the Employee Stock Purchase Plan. Prior to the two for one split, the Company had issued 459 Common Shares to its employees and had 9,541 shares, $15 par reserved for the purpose of the plan. Applicant now requests that the Commission amend its previous order so as to authorize an additional 10,000 shares of Common Stock, $10 par for issuance, under the plan, or a total of 20,000 shares, $10 par for issuance pursuant to Applicant's Employee Stock Purchase Plan.

Applicant also requests exemption from the Commissions' competitive bidding requirements.

Any person desiring to be heard or to make any protest with reference to said application should on or before June 30, 1964, file with the Federal Power Commission, Washington, D.C., 20426, petitions or protests in accordance with the requirements of the Commission's rules of practice and procedure (18 CFR 1.8 or 1.10). The application is on file and available for public inspection.

JOSEPH H. GUTRIDE,
Secretary.

[F.R. Doc. 64–5878; Filed, June 12, 1964; 8:47 a.m.]

[Docket No. E–7168]

NORTHERN STATES POWER CO. (MINN.)

Notice of Application

JUNE 5, 1964.

Take notice that on June 1, 1964, an application was filed with the Federal Power Commission, pursuant to section 204 of the Federal Power Act by Northern States Power Company (Applicant), a corporation organized under the laws of the State of Minnesota and doing business in the States of Minnesota, North Dakota and South Dakota, with its principal business office at Minneapolis, Minnesota, seeking an order authorizing the issuance of 150,000 shares of Cumulative Preferred Stock, with a par value of $100 per share.

Applicant proposes to sell the Preferred Stock by competitive bidding, the shares to be designated "Cumulative Preferred Stock, $-------- Series". The annual dividend rate on said shares shall be determined by the competitive bidding. Each proposal for the purchase of said Preferred Stock must be accompanied by a deposit of $450,000, specify the dividend rate (which rate must be a multiple of one cent) for the Preferred Stock and be for the purchase of all of the stock at a price of not less than $100 or more than $102.75 per share. Unless Applicant rejects all proposals, it will accept the proposal which provides it with the lowest cost of money. The stock is to be issued on July 30, 1964.

Applicant states that the net proceeds, amounting to approximately $15,000,000 received from the issuance and sale of the aforesaid Preferred Stock will be used to pay an equal amount of 1964 bank loans, heretofore authorized by the Commission (Docket Nos. E–7101 and E–7048), which at the time of issuance and delivery of the new Preferred Stock, it is estimated will aggregate approximately $19,000,000 outstanding. These loans replenished the general funds of Applicant which were reduced by 1964 construction expenditure payments. Applicant's construction program for 1964 is estimated at $50,200,000 which is broken down as follows: $34,080,000 for electric production, transmission and distribution facilities, $6,020,000 for gas facilities, $181,000 for heating facilities, $640,000 for telephone facilities and $9,280,000 for general expenditures.

Any person desiring to be heard or to make any protest with reference to said application should on or before June 26, 1964, file with the Federal Power Commission, Washington, D.C., 20426, petitions or protests in accordance with the requirements of the Commission's rules of practice and procedure (18 CFR 1.8 or 1.10). The application is on file and available for public inspection.

JOSEPH H. GUTRIDE,
Secretary.

[F.R. Doc. 64–5879; Filed, June 12, 1964; 8:47 a.m.]

[Docket No. E-7165]

SOUTHERN CALIFORNIA EDISON CO. AND DESERT ELECTRIC COOPERATIVE, INC.

Notice of Application

JUNE 5, 1964.

Take Notice that on May 25, 1964 an application was filed with the Federal Power Commission, pursuant to section 203 of the Federal Power Act, by Southern California Edison Company (Edison), a corporation organized under the laws of the State of California and doing business in the States of California, Arizona and Nevada, with its principal office in Los Angeles, California seeking authority to acquire and merge or consolidate with its facilities, all the facilities of the Desert Electric Cooperative, Inc. (Coop). Coop is a corporation organized under the laws of the State of California and doing business in that State with its principal business office at Twentynine Palms, California. Coop joined in the application seeking authority to dispose of its facilities or, in the alternative, an order declaring that the Commission has no authority over the disposition by Coop of its facilities.

Edison is engaged in the generation, purchase, transmission, distribution and sale of electric energy in parts of the Southern California counties of Fresno, Imperial, Inyo, Kern, Kings, Los Angeles, Madera, Mono, Orange, Riverside, San Bernardino, Santa Barbara, Tulare and Ventura in the State of California and in the counties of Nye and Esmeralda in the State of Nevada. Edison owns a steam electric generating plant located near Yuma, Arizona, the output of which it shares with Arizona Public Service Company, and Imperial Irrigation District. Edison does not serve the public in Arizona. As of December 31, 1963 Edison had total assets in excess of $1,800,000,000 and gross operating revenues in excess of $423,000,000.

Coop is engaged in the distribution and sale of electric energy in two isolated areas adjacent to the Twentynine Palms but not including that community. Coop, as of December 31, 1963 has total assets and other debits of approximately 2,350,000 and gross operating revenues of 253,564. It purchases all its energy requirements from Edison.

The proposed acquisition is to be carried out in accordance with the terms and conditions of an Agreement of Purchase and Sale dated April 2, 1964 for an amount equal to the obligation of the Coop to the Rural Electrification Administration (REA) plus an amount equal to the unrefunded membership fees collected and held by the Coop. According to the application, the price calculated on that basis, exceeds the book value of the property to be transferred.

Applicants submit that the acquisition by Edison of the Desert Electric facilities is in the public interest for the following reasons:

> As shown by the application Desert Electric serves two separate areas, one lying to the west and the other to the east of the Community of Twentynine Palms. These separate areas are completely surrounded by Edison's service territory. The integration of Desert Electric's territory with that of Edison will eliminate these artificial islands as barricades to future orderly system planning, will prevent future duplication of facilities near the periphery of Desert Electric's present territory, will end confusion in the minds of prospective customers as to which utility to apply to for service and will eliminate dissatisfaction on the part of the inhabitants of Desert Electric's present territory over the substantial rate differential between areas served by Desert Electric and the surrounding areas served by Edison. Elimination of a separate corporate structure to serve Desert Electric's relatively small (approximately 500 square miles) territory should produce additional economies.

Applicants also submit that the proposed transaction is in the best interests of Desert Electric, its members, its employees and the area that it presently serves for the following reasons:

> Upon completion of the transaction, Desert Electric will be relieved of a presently large, and potentially larger, indebtedness to REA. Its members will receive a refund of their membership fees and will enjoy substantially lower electric rates. Its employees will be offered positions with a large, well established utility at no less pay than they are presently receiving and will have a much greater opportunity for advancement than with Desert Electric. The development of the area presently served by Desert Electric will be promoted by the availability of an abundant supply of economical electric energy.

Any person desiring to be heard or to make any protest with reference to said application should, on or before the 6th day of July, 1964, file with the Federal Power Commission, Washington, D.C., 20426, petitions or protests in accordance with the requirements of the Commission's rules of practice and procedure (18 CFR 1.8 or 1.10). The application is on file and available for public inspection.

JOSEPH H. GUTRIDE,
Secretary.

[F.R. Doc. 64-5880; Filed, June 12, 1964; 8:47 a.m.]

DEPARTMENT OF LABOR

Office of the Secretary

SOUTH DAKOTA EMPLOYMENT SECURITY DEPARTMENT

Notice of Opportunity for Hearing

Whereas, on the 29th day of December 1936, the South Dakota Employment Security Law was approved by the Social Security Board pursuant to the provisions of section 903(a) of the Social Security Act, now section 3304(a) of the Internal Revenue Code of 1954; and

Whereas, section 3304(c) of the Internal Revenue Code provides:

> *Certification.* On December 31 of each taxable year the Secretary of Labor shall certify to the Secretary [of the Treasury] each State whose law he has previously approved, except that he shall not certify any State which, after reasonable notice and opportunity for hearing to the State agency, the Secretary of Labor finds has amended its law so that it no longer contains the provisions specified in subsection (a) or has with respect to such taxable year failed to comply substantially with any such provision and such finding has become effective. Such finding shall become effective on the 90th day after the governor of the State has been notified thereof, unless the State has before such 90th day so amended its law that it will comply substantially with the Secretary of Labor's interpretation of the provision of subsection (a), in which event such finding shall not become effective. No finding of a failure to comply substantially with the provision in State law specified in paragraph (5) of subsection (a) shall be based on an application or interpretation of State law with respect to which further administrative or judicial review is provided for under the laws of the State.

and

Whereas, section 303(a)(5) of the Social Security Act, insofar as is here pertinent, provides:

> SEC. 303. (a) The Secretary of Labor shall make no certification for payment to any State unless he finds that the law of such State, approved by him under the Federal Unemployment Tax Act, includes provision for—
>
> * * * * *
>
> (5) Expenditure of all money withdrawn from an unemployment fund of such State, in the payment of unemployment compensation;

and

Whereas, the South Dakota Employment Security Law has been amended by Chapter 125 of South Dakota Session Laws of 1963 (Senate Bill 89) to provide that all claimants for unemployment compensation with base period wages of $6,000 or more are to be disqualified for unemployment compensation for stated periods, ranging from 7 to 13 weeks; and

Whereas, Senate Bill 179 approved February 13, 1964, makes Chapter 125 effective on January 15, 1964, but inoperative until July 1, 1964, unless the Governor thereafter takes the action prescribed to make the law inoperative; and

Whereas, as a result of said enactments a question is presented whether the State has amended its law so that it no longer contains the provisions specified in section 3304(a)(4) of the Internal Revenue Code; and

Whereas, as a further result of said enactments a question is presented whether the South Dakota Employment Security Law continues to include the provisions required by section 303(a)(5) of the Social Security Act;

Now, therefore, pursuant to the provisions of section 3304(c) of the Internal Revenue Code, notice is hereby given that an opportunity for hearing will be provided to the South Dakota Employment Security Department, beginning at 10 o'clock in the morning of July 7, 1964, in Room 3428, Department of Labor, 14th Street and Constitution Avenue NW., Washington, D.C., on the question of whether the State of South Dakota has amended its law so that it no longer contains the provisions specified in section 3304(a)(4). Although no notice or opportunity for hearing is required before the Secretary withholds certification for payment to a State under section 303(a) of the Social Security Act, the hearing to be held pursuant to section 3304(c) of the Internal Revenue Code will cover the further question whether the South Dakota Employment Security Law continues to include the provisions required by section 303(a)(5) of the Social Security Act. Upon the basis of the evidence and legal arguments adduced at said hearing, it will be determined whether or not the State of South Dakota may be certified to the Secretary of the Treasury, as provided in section 3304(c) of the Internal Revenue Code and section 302(a) of the Social Security Act.

The proceedings will be conducted in accordance with the following rules:

(1) Clifford P. Grant, a hearing examiner, is hereby designated to preside over the hearing.

(2) The parties of record shall be the South Dakota Employment Security Department and the United States Department of Labor.

(3) Participation by any person other than the parties of record shall be limited to oral argument as provided in paragraph 10 below and to the submittal of a brief as provided in paragraph 11 below, or to either as he chooses.

(4) The hearing will be conducted in an informal but orderly and expeditious manner. The hearing examiner will regulate all matters relating to the course and conduct of the hearing.

(5) The representative of the Department of Labor will make an opening statement as to the nature of the hearing and the matters in issue. This will be followed by an opportunity for the representative of the South Dakota Employment Security Department to do likewise.

(6) Parties of record thereupon shall have the right to present oral and documentary evidence and cross-examine witnesses. Technical rules of evidence shall not apply. The hearing examiner will rule upon offers of proof and the admissibility of evidence, and receive relevant evidence. He may exclude irrelevant, immaterial or unduly repetitious evidence, and may examine witnesses. All written statements, charts, tabulations, and similar data offered in evidence at the hearing shall, upon a showing satisfactory to the hearing examiner of their authenticity, relevancy, and materiality, be received in evidence.

(7) At any stage of the hearing the hearing examiner may call for further evidence upon any matter. After the record has been closed no further evidence shall be taken except at request of the Secretary of Labor, unless provision has been made at the hearing for the later receipt of such evidence. In the event that the Secretary shall cause the hearing to be reopened for the purpose of receiving further evidence, due and reasonable notice of the time and place fixed for any taking of testimony shall be given to all parties of record.

(8) The hearing shall be stenographically recorded. The transcript will be available to any person, at prescribed rates.

(9) Any material offered in evidence and any proposals submitted pursuant to paragraph 12 shall be tendered in triplicate.

(10) After all testimony has been taken and all evidence has been received, the hearing examiner may, upon request, permit any party of record or any other interested person to present oral argument upon the matters in issue. Any interested person other than a party of record who wishes to present oral argument shall file in the Office of the Chief Hearing Examiner, Room 4410, Department of Labor, 14th Street and Constitution Avenue NW., Washington, D.C., 20210, on or before July 1, 1964, a written or telegraphic request setting forth his name and the persons or groups, if any, whom he represents; the argument of any such person shall be limited to 30 minutes. To the extent that there is oral argument, it shall be in the following order: opening argument for the United States Department of Labor, opening argument for the South Dakota Employment Security Department, arguments for interested persons other than parties of record, closing argument for the South Dakota Employment Security Department, and closing argument for the United States Department of Labor. All oral arguments shall be transcribed and made a part of the record.

(11) Any party of record or any other interested person may file a brief on the issues herein. Such brief shall be filed in quadruplicate in the Office of the Chief Hearing Examiner no later than twenty-one (21) days after the transcript of the hearing is available. The Office of the Chief Hearing Examiner will forward to the parties of record a copy of each brief filed.

(12) Proposed findings of fact and conclusions of law together with supporting reasons therefor may be submitted to the Office of the Chief Hearing Examiner by any party of record within twenty-one (21) days after the transcript of the hearing is available.

(13) After the time for the filing of briefs, proposed findings of fact and conclusions of law, the hearing examiner shall prepare a recommended decision containing findings of fact and conclusions of law. This recommended decision shall be served upon the parties of record who may, within fifteen (15) days from the date of its receipt, file in the Office of the Chief Hearing Examiner a statement in writing setting forth any exceptions they may have to such decision together with supporting reasons therefor.

(14) After the time for filing exceptions to the hearing examiner's recommended decision, the hearing examiner shall certify to the Secretary of Labor the entire record of the proceedings together with his recommended decision. The Secretary shall then render his decision in the matter.

Signed at Washington, D.C., this 9th day of June 1964.

W. WILLARD WIRTZ,
Secretary of Labor.

[F.R. Doc. 64-5904; Filed, June 12, 1964; 8:49 a.m.]

INTERSTATE COMMERCE COMMISSION

FOURTH SECTION APPLICATIONS FOR RELIEF

JUNE 10, 1964.

Protests to the granting of an application must be prepared in accordance with Rule 1.40 of the general rules of practice (49 CFR 1.40) and filed within 15 days from the date of publication of this notice in the FEDERAL REGISTER.

LONG-AND-SHORT HAUL

FSA No. 39071: *Sugar from Hereford, Tex.* Filed by Southwestern Freight Bureau, agent (No. B-8558), for interested rail carriers. Rates on sugar, beet, or cane, in carloads, from Hereford, Tex., to points in Illinois, Iowa, Kansas, Missouri, Nebraska, and Wisconsin.

Grounds for relief: Market competition.

Tariff: Supplement 12 to Southwestern Freight Bureau, agent, tariff I.C.C. 4514.

FSA No. 39072: *Ferro alloys from Emco, Ala.* Filed by O. W. South, Jr., agent (No. A4525), for interested rail carriers. Rates on ferro-manganese, ferro-silicon, and silico-manganese, in carloads, from Emco, Ala., to specified points in Pennsylvania, also East Liverpool, Ohio.

Grounds for relief: Barge-truck competition.

Tariff: Supplement 32 to Southern Freight Association, agent, tariff I.C.C. S-308.

By the Commission.

[SEAL] HAROLD D. MCCOY,
Secretary.

[F.R. Doc. 64-5875; Filed, June 12, 1964; 8:47 a.m.]

CUMULATIVE CODIFICATION GUIDE—JUNE

The following numerical guide is a list of the parts of each title of the Code of Federal Regulations affected by documents published to date during June.

1 CFR

	Page
CFR Checklist	7139

3 CFR

	Page
PROCLAMATIONS:	
3593	7281

5 CFR

	Page
213	7235, 7380, 7505
PROPOSED RULES:	
890	7327

7 CFR

	Page
1	7311
28	7374
81	7585
301	7451
401	7413
718	7311
722	7312
724	7588
728	7139
908	7375, 7589
910	7235, 7375, 7590
916	7139–7141, 7590
917	7141–7143, 7452, 7505
923	7375
965	7143, 7376, 7590
980	7143, 7377, 7591
1002	7283
1032	7235
1040	7377
1042	7378
1043	7379
1074	7235
1421	7591
1443	7594
1485	7312
PROPOSED RULES:	
51	7242, 7327
1001	7150
1006	7150
1007	7150
1014	7150
1015	7150
1030	7426, 7551
1031	7551
1032	7426
1035	7551
1037	7557
1062	7426
1067	7426
1125	7246
1131	7286

8 CFR

	Page
214	7413
236	7236
242	7236
246	7236
PROPOSED RULES:	
3	7473

9 CFR

	Page
74	7236
78	7237
94	7237

10 CFR

	Page
PROPOSED RULES:	
30	7393

12 CFR

	Page
1	7283, 7546, 7594
4	7413
508	7417
545	7417
563	7417

13 CFR

	Page
107	7144
121	7312
PROPOSED RULES:	
107	7151

14 CFR

	Page
1 [New]	7452
13	7452
14	7458
33 [New]	7453
35 [New]	7458
61 [New]	7594
71 [New]	7145, 7146, 7237, 7238, 7313, 7314, 7418, 7419, 7505, 7595.
73 [New]	7314, 7596
75 [New]	7238, 7596
97 [New]	7365, 7419, 7540
99 [New]	7146
302	7314
507	7238, 7315, 7419, 7596
551	7459
PROPOSED RULES:	
3	7475
4b	7170
23 [New]	7475
25 [New]	7170
61 [New]	7150
71 [New]	7328, 7428, 7515, 7516, 7604
73 [New]	7429
75 [New]	7328, 7329, 7428, 7604
91 [New]	7605
507	7247, 7605, 7606

15 CFR

	Page
201	7316
371	7420

16 CFR

	Page
13	7147–7149, 7460, 7506–7508
152	7460
402	7316
PROPOSED RULES:	
69	7568

17 CFR

	Page
231	7317
240	7239, 7283, 7380

18 CFR

	Page
PROPOSED RULES:	
141	7330
260	7330

19 CFR

	Page
3	7420
6	7420
10	7420
PROPOSED RULES:	
1	7327

21 CFR

	Page
1	7284
3	7382
8	7421
37	7240
120	7597
121	7240, 7318, 7382, 7461, 7642, 7597
130	7149
146	7625, 7642
148	7626
148a	7627
148b	7629
148c	7631
148d	7634
148e	7643
148f	7636
148h	7637
148j	7653
148m	7640
148o	7655
PROPOSED RULES:	
15	7392
16	7247
121	7427, 7473

24 CFR

	Page
203	7508
231	7508

25 CFR

	Page
221	7284
PROPOSED RULES:	
221	7286

26 CFR

	Page
1	7421
PROPOSED RULES:	
1	7426, 7513

28 CFR

	Page
0	7383, 7422, 7423

29 CFR

	Page
603	7149
657	7598
PROPOSED RULES:	
516	7289
551	7289

30 CFR

	Page
10	7318
11	7319
12	7319
13	7319
14	7319
14a	7320
15	7320
16	7320
17	7321
18	7321
19	7321
20	7321
21	7321
22	7322
23	7322
24	7322
25	7322
26	7322
27	7322
31	7322
32	7323
33	7323
34	7323
35	7323
36	7323

32 CFR

	Page
706	7546

33 CFR

	Page
3	7424
203	7383

36 CFR

	Page
7	7324

37 CFR

	Page
PROPOSED RULES:	
1	7150

38 CFR

	Page
2	7546
3	7547

39 CFR

	Page
168	7509

41 CFR

	Page
8-7	7548
8-14	7548
8-51	7548
8-52	7548
9-5	7549
11-1	7240, 7384
11-5	7384
11-7	7384
11-60	7325

43 CFR

	Page
PUBLIC LAND ORDERS:	
3401	7285
3402	7549
3403	7549

45 CFR

	Page
142	7598
160	7600
401	7510

46 CFR

	Page
2	7345, 7388
10	7346
25	7346, 7388
30	7347
31	7347
32	7347
33	7349
35	7349
50	7349
51	7349
52	7350
55	7350
57	7351
59	7352
70	7352
71	7352
72	7353
73	7353
75	7353
76	7353
78	7353
90	7353
91	7353
98	7354
110	7355
111	7356
112	7358
113	7358
160	7358, 7388
162	7360
164	7360

46 CFR—Continued

	Page
167	7361
176	7362
180	7390
182	7362
187	7362
PROPOSED RULES:	
290	7392
510	7429

47 CFR

	Page
2	7390
13	7462
73	7463, 7468, 7471, 7535
PROPOSED RULES:	
1	7292
21	7151
25	7395
31	7474
34	7396
35	7396
91	7151

49 CFR

	Page
95	7425
97	7241
170	7425, 7510, 7511
176	7390

50 CFR

	Page
10	7511
PROPOSED RULES:	
263	7568

FEDERAL REGISTER

Area Code 202 Phone 963-3261

Published daily, Tuesday through Saturday (no publication on Sundays, Mondays, or on the day after an official Federal holiday), by the Office of the Federal Register, National Archives and Records Service, General Services Administration (mail address National Archives Building, Washington, D.C. 20408), pursuant to the authority contained in the Federal Register Act, approved July 26, 1935 (49 Stat. 500, as amended; 44 U.S.C., ch. 8B), under regulations prescribed by the Administrative Committee of the Federal Register, approved by the President (1 CFR Ch. I). Distribution is made only by the Superintendent of Documents, Government Printing Office, Washington, D.C. 20402.

The FEDERAL REGISTER will be furnished by mail to subscribers, free of postage, for $1.50 per month or $15.00 per year, payable in advance. The charge for individual copies (minimum 15 cents) varies in proportion to the size of the issue. Remit check or money order, made payable to the Superintendent of Documents, Government Printing Office, Washington, D.C. 20402.

The regulatory material appearing herein is keyed to the CODE OF FEDERAL REGULATIONS, which is published, under 50 titles, pursuant to section 11 of the Federal Register Act, as amended. The CODE OF FEDERAL REGULATIONS is sold by the Superintendent of Documents. Prices of books and pocket supplements are listed in the first FEDERAL REGISTER issue of each month.

There are no restrictions on the republication of material appearing in the FEDERAL REGISTER or the CODE OF FEDERAL REGULATIONS.

Pages 7625–7657

PART II

FEDERAL REGISTER

VOLUME 29 NUMBER 116

Washington, Saturday, June 13, 1964

Title 21—FOOD AND DRUGS

Chapter I—Food and Drug Administration, Department of Health, Education, and Welfare

SUBCHAPTER C—DRUGS

TESTS AND METHODS OF ASSAY AND CERTIFICATION OF ANTIBIOTIC DRUGS SUBJECT TO DRUG AMENDMENTS OF 1962

The Commissioner of Food and Drugs has evaluated the views and comments received in response to the notice of proposed rule-making published in the FEDERAL REGISTER of May 2, 1963 (28 F.R. 4411–4429, inclusive), and has concluded that the following regulations should issue for the certification of those antibiotic drugs subject to the Drug Amendments of 1962 (76 Stat. 785–787; Public Law 87–781). Therefore, pursuant to the provisions of the Federal Food, Drug, and Cosmetic Act (sec. 507, 59 Stat. 463, as amended; 21 U.S.C. 357), and under the authority delegated to him by the Secretary of Health, Education, and Welfare (21 CFR 2.90; 29 F.R. 471), the following amendments are ordered:[1]

PART 146—GENERAL REGULATIONS FOR THE CERTIFICATION OF ANTIBIOTIC AND ANTIBIOTIC-CONTAINING DRUGS

1. Section 146.1 is amended as follows:

a. By revising the section heading to read:

§ 146.1 Definitions and interpretations applicable to all certifiable antibiotic drugs.

b. By adding to paragraph (a) the following new subparagraphs:

(8) Each of the antibiotic substances produced by the growth of Streptomyces canus, and each of the same substances produced by any other means, is a kind of amphomycin.

(9) Each of the antibiotic substances produced by the growth of Streptomyces nodosus, and each of the same substances produced by any other means, is a kind of amphotericin.

(10) Each of the antibiotic substances produced by the growth of Bacillus polymyxa var. colistinus, and each of the same substances produced by any other means, is a kind of colistin.

(11) Each of the antibiotic substances produced by the growth of Streptomyces orchidaceus, and each of the same substances produced by any other means, is a kind of cycloserine.

(12) Each of the antibiotic substances produced by the growth of Streptomyces erythreus, and each of the same substances produced by any other means, is a kind of erythromycin.

(13) Each of the antibiotic substances produced by the growth of Bacillus brevis, and each of the same substances produced by any other means, is a kind of gramicidin.

(14) Each of the antibiotic substances produced by the growth of Penicillium patulum or Penicillium griseofulvum, and each of the same substances produced by any other means, is a kind of griseofulvin.

(15) Each of the antibiotic substances produced by the growth of Streptomyces kanamyceticus, and each of the same substances produced by any other means, is a kind of kanamycin.

(16) Each of the antibiotic substances produced by the growth of Streptomyces fradiae, and each of the same substances produced by any other means, is a kind of neomycin.

(17) Each of the antibiotic substances produced by the growth of Streptomyces niveus (known also as Streptomyces spheroides), and each of the same substances produced by any other means, is a kind of novobiocin.

(18) Each of the antibiotic substances produced by the growth of Streptomyces noursei, and each of the same substances produced by any other means, is a kind of nystatin.

(19) Each of the antibiotic substances produced by the growth of Streptomyces antibioticus, and each of the same substances produced by any other means, is a kind of oleandomycin.

(20) [Reserved]

(21) Each of the antibiotic substances produced by the growth of Streptomyces rimosus, and each of the same substances produced by any other means, is a kind of oxytetracycline.

(22) Each of the antibiotic substances produced by the growth of Streptomyces rimosus var. paromomycinus, and each of the same substances produced by any other means, is a kind of paromomycin.

(23) Each of the antibiotic substances produced by the growth of Bacillus polymyxa, and each of the same substances produced by any other means, is a kind of polymyxin.

(24) Each of the antibiotic substances produced by the growth of Nocardia lurida, and each of the same substances produced by any other means, is a kind of ristocetin.

(25) Each of the mixtures of antibiotic substances produced by the growth of Bacillus brevis, and each of the same mixtures of substances produced by any other means, is a kind of tyrothricin.

(26) Each of the antibiotic substances produced by the growth of Streptomyces orientalis, and each of the same substances produced by any other means, is a kind of vancomycin.

(27) Each of the antibiotic substances produced by the growth of Streptomyces puniceus or Streptomyces floridae or Actinomyces vinaceus, and each of the same substances produced by any other means, is a kind of viomycin.

c. By adding to paragraph (b) the following new subparagraphs:

(10) The term "amphomycin master standard" means a specific lot of amphomycin designated by the Commissioner as the standard of comparison in determining the potency of the amphomycin working standard.

(11) The term "amphotericin A master standard" means a specific lot of amphotericin A designated by the Commissioner as the standard of comparison in determining the potency of the amphotericin A working standard. The term "amphotericin B master standard" means a specific lot of amphotericin B designated by the Commissioner as the standard of comparison in determining the potency of the amphotericin B working standard.

(12) The term "colistin master standard" means a specific lot of colistin designated by the Commissioner as the standard of comparison in determining the potency of the colistin working standard.

---

[1] Certain portions of the proposal will be covered by a subsequent order.

(13) The term "colistimethate master standard" means a specific lot of colistimethate designated by the Commissioner as the standard of comparison in determining the potency of the colistemethate working standard.

(14) The term "cycloserine master standard" means a specific lot of cycloserine designated by the Commissioner as the standard of comparison in determining the potency of the cycloserine working standard.

(15) The term "erythromycin master standard" means a specific lot of erythromycin designated by the Commissioner as the standard of comparison in determining the potency of the erythromycin working standard.

(16) The term "gramicidin master standard" means a specific lot of gramicidin designated by the Commissioner as the standard of comparison in determining the potency of the gramicidin working standard.

(17) The term "griseofulvin master standard" means a specific lot of griseofulvin designated by the Commissioner as the standard of comparison in determining the potency of the griseofulvin working standard.

(18) The term "kanamycin master standard" means a specific lot of kanamycin designated by the Commissioner as the standard of comparison in determining the potency of the kanamycin working standard.

(19) The term "neomycin master standard" means a specific lot of neomycin designated by the Commissioner as the standard of comparison in determining the potency of the neomycin working standard.

(20) The term "novobiocin master standard" means a specific lot of novobiocin designated by the Commissioner as the standard of comparison in determining the potency of the novobiocin working standard.

(21) The term "nystatin master standard" means a specific lot of nystatin designated by the Commissioner as the standard of comparison in determining the potency of the nystatin working standard.

(22) The term "oleandomycin master standard" means a specific lot of oleandomycin designated by the Commissioner as the standard of comparison in determining the potency of the oleandomycin working standard.

(23) The term "oxytetracycline master standard" means a specific lot of oxytetracycline designated by the Commissioner as the standard of comparison in determining the potency of the oxytetracycline working standard.

(24) The term "paromomycin master standard" means a specific lot of paromomycin designated by the Commissioner as the standard of comparison in determining the potency of the paromomycin working standard.

(25) The term "polymyxin B master standard" means a specific lot of polymyxin B designated by the Commissioner as the standard of comparison in determining the potency of the polymyxin B working standard.

(26) The term "ristocetin A master standard" means a specific lot of ristocetin A designated by the Commissioner as the standard of comparison in determining the potency of the ristocetin A working standard. The term "ristocetin B master standard" means a specific lot of ristocetin B designated by the Commissioner as the standard of comparison in determining the potency of the ristocetin B working standard.

(27) The term "vancomycin master standard" means a specific lot of vancomycin designated by the Commissioner as the standard of comparison in determining the potency of the vancomycin working standard.

(28) The term "viomycin master standard" means a specific lot of viomycin designated by the Commissioner as the standard of comparison in determining the potency of the viomycin working standard.

2. In § 146.3 *Certification*, paragraph (c) is amended by changing the phrase "in Parts 141a to 141e and § 147.2 of this chapter" to read "issued under this chapter."

3. The introduction to § 146.10 is changed to read:

§ 146.10 Antibiotics for export.

Drugs containing antibiotic substances subject to certification under section 507 of the act and intended for export will be certified notwithstanding failure to meet the labeling requirements of the applicable monographs if the labeling used for such drugs complies with the following conditions:

* * * * *

4. Section 146.12 *Antibiotic drugs exempted from certification requirements under section 507(c) of the Federal Food, Drug, and Cosmetic Act* is amended in the following respects:

a. By changing the first sentence of paragraph (a) to read:

(a) Section 507(a) of the Federal Food, Drug, and Cosmetic Act directs the Secretary of Health, Education, and Welfare to promulgate regulations to provide for the certification of batches of drugs composed wholly or partly of any kind of antibiotic substance. * * *

b. By changing the item "Antibiotics for fish diseases" in paragraph (b)(3) to read:

Antibiotics for diseases of fish not intended for use as food.

5. Section 146.22 *Exemptions for manufacturing use* is amended by changing paragraph (a) to read:

(a) Except as provided by paragraphs (c) and (d) of this section, a shipment or other delivery of any certifiable antibiotic drug subject to the regulations in this chapter that is packed in containers of not less than 10,000,000 units of penicillin or 10 grams each of one of the other antibiotic drugs shall be exempt, during the time of introduction into and movement in interstate commerce and the time of holding in the establishment where it is so used, from the requirements of section 502(l) of the act, if it conforms to the standards prescribed therefor by the section of the regulations in this chapter which is specifically applicable to such other drug, if the label of each container bears the batch mark of the drug, the number of units or grams per package, and the date on which the latest assay of the drug was completed, and if the person who introduced each shipment or delivery into interstate commerce holds a permit from the Commissioner authorizing shipment for manufacturing use in such establishment.

6. Section 146.24 is amended as follows:

a. By changing the section heading and the introduction to the section to read:

§ 146.24 Antibiotic powders for diagnostic use.

Dry powders of antibiotic substances, with or without suitable buffer substances and diluents, packaged for dispensing and intended for use solely in laboratory procedures in connection with the diagnosis or treatment of disease and conspicuously so labeled shall be exempt from the certification requirements of sections 502(l) and 507 of the act if they comply with all the following conditions:

b. By changing paragraph (a) to read:

(a) The potency and moisture content of the antibiotic used in the manufacture of the powder and the moisture content of the powder comply with the standards prescribed for the antibiotic by the specific regulations issued in this chapter.

7. Section 146.25 *Antibiotic drugs for use in medicated animal feed* * * * is amended by changing the phrase "regulations in this chapter" in the introduction to the section to read: "regulations in Parts 146a, 146b, 146c, 146d, and 146e of this chapter".

8. Title 21 is amended by adding thereto the following new parts:

PART 148—ANTIBIOTIC DRUGS SUBJECT TO CERTIFICATION UNDER THE DRUG AMENDMENTS OF 1962

Sec.
148.1 Definitions and interpretations.
148.2 Packaging requirements.
148.3 Labeling requirements.
148.4 Requests for certification; check tests and assays; samples.
148.5 Fees.

AUTHORITY: The provisions of this Part 148 issued under sec. 507, 59 Stat. 463, as amended 76 Stat. 785, 786, 787; 21 U.S.C.A. 357.

§ 148.1 Definitions and interpretations.

The definitions and interpretations of terms found in § 146.1 of this chapter apply also to this Part 148 and to Parts 148a–148z of this chapter.

§ 148.2 Packaging requirements.

Each drug described in Parts 148a to 148z, inclusive, of this chapter shall be packaged in immediate containers that comply with the requirements described in Parts 146a to 146e, inclusive, of this chapter for the immediate containers used to package the same dosage form unless otherwise required for the drug by specific regulations.

§ 148.3 Labeling requirements.

(a) If it is packaged for dispensing:

(1) It shall be labeled in accordance with the requirements prescribed by § 1.106(b) of this chapter, issued under section 502(f) of the act, unless the regulations pertaining to such drug specifically exempt it from such requirements.

(2) Its labeling shall bear any additional information required for the drug by specific regulations.

(3) Each package shall bear on its outside wrapper or container and the immediate container an expiration date prescribed for the drug by specific regulations, except that the date may be used that is 18, 24, 30, 36, 42, 48, 54, or 60 months after the month during which the batch was certified if the person who requests certification has submitted to the Commissioner results of tests and assays showing that such drug as prepared by him is stable for such period of time. If the manufacturer or repacker of the drug has been exempted from the certification requirements, such date shall be the number of months after the month during which the batch was last assayed and released by the manufacturer or repacker. If an expiration date is used that is longer than the minimum date provided for the drug by specific regulations, it may be used only if the manufacturer has submitted information to the Commissioner adequate to prove that the drug is stable for such time.

(b) If it is packaged solely for manufacturing use or for repacking, each package shall bear on its outside wrapper or container and the immediate container, the following:

(1) The number of units or micrograms of activity per milligram or per gram, and the number of grams of kilograms in the immediate container.

(2) The batch mark.

(3) The statement "Caution: Federal law prohibits dispensing without prescription."

(4) The statement "For manufacturing use," "For repacking," or "For manufacturing use or repacking," and, if it is not sterile, the statement "nonsterile."

(5) The required expiration date.

§ 148.4 Requests for certification; check tests and assays; samples.

In addition to complying with the requirements of § 146.2 of this chapter, a person who requests certification or check tests and assays of a batch shall submit with his request the following information and samples:

(1) The batch mark of the drug.

(2) The quantity of each ingredient used in making the batch.

(3) The size of the batch, including the number of containers of each size in the batch.

(4) The date of the latest assay of the batch.

(5) The results of tests and assays made by or for him on the batch as required for the drug by specific regulations.

(6) The batch mark(s) of the antibiotic(s) used in making the batch.

(7) Unless previously submitted, the results of tests and assays made by or for him on the antibiotic(s) used in making the batch as required by specific regulations.

(8) The number of accurately representative samples that are required for the batch by specific regulations: In the case of drugs such as dry powders, solutions, ointments, and suspensions, the sample shall be collected by taking single immediate containers, before or after labeling, at such intervals throughout the entire time of packaging the batch that the quantities packaged during the intervals are approximately equal. In no case, however, shall more than 5,000 immediate containers have been packaged during each such interval of sampling, except for a sample collected for sterility testing. In the case of drugs such as tablets or other such unit dosage forms, the sample shall be collected by taking single tablets at such intervals throughout the entire time of tableting the batch that the quantities tableted during the intervals are approximately equal. In no case, however, shall more than 5,000 tablets have been tableted during each interval of sampling, except for a sample collected for time of disintegration. If the person who packages the tablets into dispensing-size containers is not the manufacturer, such sample shall be collected throughout the entire time of packaging the batch into such containers.

(9) Unless previously submitted, the number of accurately representative samples that are required for the antibiotic(s) used in making the batch by the regulations specifically relating to such drug.

(10) In connection with contemplated requests for certification of repacked batches or batches of another drug in the manufacture of which it is to be used, the manufacturer of a batch which is to be so repackaged or used may request the Commissioner to make check tests and assays on a representative sample of such batch. From the information submitted may be omitted results of tests and assays not required for the batch when used in such other drug. The Commissioner shall report to such manufacturer results of such check tests and assays as are so requested.

§ 148.5 Fees.

The fee for the services rendered with respect to each batch certified under the regulations in Parts 148a–148z, inclusive, of this chapter shall accompany the request for certification, or the request for check tests and assays, unless such fee is covered by an advance deposit maintained in accordance with § 146.8(d) of this chapter. Such fee shall be that required for the drug by the specific regulations, plus an additional 30 percent of whatever that fee may be. Also, if the Commissioner considers that investigations other than examination of such samples are necessary to determine whether or not such batch complies with the requirements of § 146.3 of this chapter for the issuance of a certificate, the fee shall include the cost of such investigations.

PART 148a—AMPHOMYCIN

Sec.

148a.1 Calcium amphomycin.
148a.2 Calcium amphomycin-neomycin sulfate-hydrocortisone acetate cream.

AUTHORITY: The provisions of this Part 148a issued under sec. 507, 59 Stat. 463 as amended; 21 U.S.C. 357.

§ 148a.1 Calcium amphomycin.

(a) *Requirements for certification*—(1) *Standards of identity, strength, quality, and purity.* Calcium amphomycin is the calcium salt of amphomycin. It is so purified and dried that:

(i) Its potency is not less than 868 micrograms of amphomycin per milligram.

(ii) Its moisture content is not more than 10 percent.

(iii) Its pH in a 2 percent aqueous suspension is not less than 6.0 and not more than 7.5.

(2) *Labeling.* It shall be labeled in accordance with the requirements of § 148.3(b) of this chapter. Its expiration date is 12 months.

(3) *Request for certification.* In addition to the requirements of § 148.4 of this chapter, each such request shall contain:

(i) Results of tests and assays on the batch for potency, moisture, and pH.

(ii) Samples required on the batch: 10 packages, each containing approximately 300 milligrams.

(4) *Fees.* $4.00 for each immediate container in the sample submitted in accordance with subparagraph (3)(ii) of this paragraph.

(b) *Tests and methods of assay*—(1) *Potency*—(i) *Cylinders (cups).* Use cylinders described in § 141a.1 of this chapter.

(ii) *Culture media.* Use ingredients that conform to the standards prescribed by the U.S.P. or N.F.

(*a*) Make nutrient agar for the base layer as follows:

Peptone	6.0 gm.
Yeast extract	3.0 gm.
Beef extract	1.5 gm.
Agar	15.0 gm.
Distilled water, q.s.	1,000.0 ml.

pH 7.0 after sterilization.

(*b*) Make nutrient agar for the seed layer as follows:

Peptone	6.0 gm.
Pancreatic digest of casein	4.0 gm.
Yeast extract	3.0 gm.
Beef extract	1.5 gm.
Dextrose	1.0 gm.
Agar	15.0 gm.
Distilled water, q.s.	1,000.0 ml.

pH 7.0 after sterilization.

In lieu of preparing the media from the individual ingredients specified in subsections (*a*) and (*b*) of this subdivision, they may be made from a dehydrated mixture which, when reconstituted with distilled water, has the same composition as such media. Minor modification of the individual ingredients specified in this subdivision are permissible if the resulting media possess growth-promoting properties at least equal to the media described.

(iii) *Preparation of suspension.* The test organism is *micrococcus flavus* (ATCC 14452). Maintain this organism on slants of nutrient agar prepared as described in subdivision (ii)(*b*) of this subparagraph and to which has been added 1 milligram of neomycin sulfate per milliliter of agar. Wash the organism from the agar slant with 3 milliliters of sterile U.S.P. saline T.S. onto a large agar surface such as that provided by a Roux bottle containing 300 milliliters of the same type of agar used for the slants. Spread the suspension of organisms over the entire agar surface with the aid of sterile glass beads. Incubate for 24 hours at 32° C. to 35° C., and then wash the resulting growth from the agar surface with 50 milliliters of sterile U.S.P. saline T.S. If an aliquot of this bulk suspension, when diluted 1:35 in the saline solution, gives 25 percent light transmission in a suitable photoelectric colorimeter with a 580-millimicron filter and a test tube with an inside diameter of 13 millimeters as an absorption cell, the bulk suspension is satisfactory for use. It may be necessary to adjust the bulk suspension by dilution, so that an aliquot of the adjusted suspension diluted 1:35 gives 25 percent light transmission. The adjusted bulk suspension, and not the 1:35 dilution of it, is used in preparing the seed layer. Incubate seeded plates to determine the quantity of the adjusted bulk suspension (usually 0.5 millimeter) that should be added to each 100 milliliters of agar to give zones of inhibition of appropriate size.

(iv) *Preparation of plates.* Add 21 milliliters of the base layer agar prepared as directed in subdivision (ii)(*a*) of this subparagraph to each Petri dish (20 millimeters x 100 millimeters). Distribute the agar evenly in the plates, cover with porcelain covers glazed on the outside, and allow it to harden. Use the plates the same day they are prepared. Add the predetermined aliquot of the adjusted bulk suspension to the agar described in subdivision (ii)(*b*) of this subparagraph which has been melted and cooled to 48° C. Mix the seeded agar thoroughly and add 4 milliliters to each of the plates containing 21 milliliters of the uninoculated agar described in subdivision (ii) (*a*) of this subparagraph. Tilt the plates to spread the agar evenly over the surface. Place six cylinders on the inoculated agar surface so that they are at approximately 60° intervals on 2.8-centimeter radius.

(v) *Working standard.* Dry an appropriate amount of the working standard for 3 hours at 60° C. and a pressure of 5 millimeters of mercury or less. Determine the dry weight and dissolve the dried standard in sufficient 0.1*M* potassium phosphate buffer, pH 8.0, to give a stock standard solution of 100 micrograms per milliliter. This should be allowed to stand overnight at room temperature in order to allow complete solution to take place. Store this stock standard solution in a refrigerator, and use for no longer than 14 days.

(vi) *Standard curve.* Prepare the daily standard curve by further diluting the 100 microgram per milliliter stock standard solution in sufficient 0.1*M* potassium phosphate buffer, pH 8, to obtain concentrations of 6.4, 8.0, 10.0, 12.5 and 15.6 micrograms per milliliter. A total of 12 plates is used in the preparation of the standard curve, three plates for each solution except the 10.0 micrograms per milliliter solution. The latter concentration is used as the reference point and is included on each plate. On each of three plates fill three cylinders with the 10.0 micrograms per milliliter standard and the other three cylinders with the concentration under test. Thus, there will be thirty-six 10.0-microgram determinations and nine determinations for each of the other points on the curve. After the plates have incubated, read the diameters of the circles of inhibition. Average the readings of the 10.0 micrograms per milliliter concentration and the readings of the point tested for each set of three plates and average also all 36 readings of the 10.0 micrograms per milliliter concentration. The average of the 36 readings of the 10.0 micrograms per milliliter concentration is the correction point for the curve. Correct the average value obtained for each point to the figure it would be if the 10.0 micrograms per milliliter reading for that set of three plates were the same as the correction point. Thus, if in correcting the 8.0-microgram concentration the average reading of the 36 readings of the 10.0 micrograms per milliliter concentration is 16.5 millimeters and the average of the 10.0 micrograms per milliliter concentration of this set of three plates is 16.3 millimeters, the correction is +0.2 millimeter. If the average readings of the 8.0 micrograms per milliliter concentration of these same three plates is 15.9 millimeters, the corrected value is then 16.1 millimeters. Plot these corrected values, including the average of the 10.0 micrograms per milliliter concentration, on 2-cycle semilog paper using the concentration in micrograms per milliliter as the ordinate (the logarithmic scale) and the diameter of the zone of inhibition as the abscissa. Draw the standard curve through these points, either by inspection or by means of the following equations:

$$L=\frac{3a+2b+c-e}{5},$$

$$H=\frac{3e+2d+c-a}{5},$$

where:

L=Calculated zone diameter for the lowest concentration of the standard curve;

H=Calculated zone diameter for the highest concentration of the standard curve;

c=Average zone diameter of 36 readings of the 10.0 micrograms per milliliter standard;

a, b, d, e=Corrected average values for the 6.4, 8.0, 12.5, and 15.6 micrograms per milliliter standard solutions, respectively.

Plot the values obtained for L and H and connect with a straight line.

(vii) *Preparation of sample.* Dissolve the sample to be tested in sufficient 0.1*M* potassium phosphate buffer, pH 8.0, to make a convenient stock solution. Further dilute in buffer to a final concentration of 10.0 micrograms per milliliter (estimated).

(viii) *Plate assay.* Use three plates for each sample. Fill three cylinders on each plate with the 10.0 micrograms per milliliter standard and three cylinders with the 10.0 micrograms per milliliter (estimated) sample, alternating standard and sample. Incubate the plates for 16 hours to 18 hours at 32° C. to 35° C., and measure the diameter of each circle of inhibition. Average the zone readings of the standard and average the zone readings of the sample on the three plates used. If the sample gives a larger average zone size than the average of the standard, add the difference between them to the 10.0-microgram zone size of the standard curve. If the average sample value is lower than the standard value, subtract the difference between them from the 10.0-microgram value on the curve. From the curve, read the potencies corresponding to these corrected values.

(2) *Moisture.* Proceed as directed in § 141a.26(e) of this chapter.

(3) *pH.* Proceed as directed in § 141a.5(b) of this chapter, using a suspension prepared by adding 20 milligrams per milliliter.

§ 148a.2 Calcium amphomycin-neomycin sulfate-hydrocortisone acetate cream.

(a) *Requirements for certification*—(1) *Standards of identity, strength, quality, and purity.* Calcium amphomycin-neomycin sulfate-hydrocortisone acetate cream is calcium amphomycin, neomycin sulfate, and hydrocortisone acetate in a suitable and harmless water-soluble cream base containing suitable buffers, emulsifiers, and preservatives. Each gram contains 5 milligrams of amphomycin, 3.3 milligrams of neomycin, and 10 milligrams of hydrocortisone acetate. The calcium amphomycin used in making the cream conforms to the standards prescribed by § 148a.1(a)(1). The neomycin sulfate used conforms to the standards prescribed by § 148i.1(a)(1)(i), (v), (vi), and (vii) of this chapter. Each other substance used, if its name is recognized in the U.S.P. or N.F., conforms to the standards prescribed therefor by such official compendium.

(2) *Labeling.* It shall be labeled in accordance with the requirements of § 148.3 of this chapter. Its expiration date is 12 months.

(3) *Request for certification.* In addition to the requirements of § 148.4 of this chapter, each such request shall contain:

(i) Results of tests and assays on:

(*a*) The calcium amphomycin used in making the batch for potency, moisture, and pH.

(*b*) The neomycin sulfate used in making the batch for potency, moisture, pH, and identity.

(*c*) The batch for amphomycin potency and neomycin sulfate potency.

(ii) Samples required:

(*a*) Calcium amphomycin used in making the batch: 10 packages, each containing approximately 300 milligrams.

(*b*) Neomycin sulfate used in making the batch; 10 packages, each containing approximately 300 milligrams.

(*c*) The batch: A minimum of 6 immediate containers.

(*d*) In case of an initial request for certification, each other ingredient used in making the batch: One package of each containing approximately 5 grams.

(4) Fees. $4.00 for each immediate container in the samples submitted in accordance with subparagraph (3)(ii)(*a*), (*b*), and (*d*) of this paragraph; $5.00 for each immediate container in

the sample submitted in accordance with subparagraph (3)(ii)(c) of this paragraph.

(b) *Tests and methods of assay*—(1) *Amphomycin content.* Proceed as directed in § 148a.1(b)(1), except in lieu of the directions in § 148a.1(b)(1)(vii), prepare the sample as follows: Accurately weigh approximately 2 grams, and place in a blending jar containing 1.0 milliliter of polysorbate 80 and sufficient 0.1*M* potassium phosphate buffer, pH 8.0, to give a final volume of 200 milliliters. Using a high-speed blender, blend the mixture for 2 minutes and then make the proper estimated dilutions using 0.1*M* potassium phosphate buffer, pH 8.0. Its content of amphomycin is satisfactory if it contains not less than 90 percent and not more than 140 percent of the number of milligrams of amphomycin per gram that it is represented to contain.

(2) *Neomycin content.* Blend the sample as described in subparagraph (1) of this paragraph and, making the proper estimated dilutions in pH 8.0 buffer, proceed as directed in § 148i.1(b)(1) of this chapter. Its content of neomycin is satisfactory if it contains not less than 90 percent and not more than 130 percent of the number of milligrams of neomycin per gram that it is represented to contain.

PART 148b—AMPHOTERICIN

Sec.
148b.1 Amphotericin B.
148b.2 Amphotericin B intravenous.

AUTHORITY: The provisions of this Part 148b issued under sec. 507, 59 Stat. 463, as amended 76 Stat. 785, 786, 787; 21 U.S.C.A. 357.

§ 148b.1 Amphotericin B.

(a) *Requirements for certification*—(1) *Standards of identity, strength, quality, and purity.* Amphotericin B is a yellow to golden-orange powder. It is insoluble in water at pH. 6.0 to 7.0, anhydrous alcohols, esters, ethers, benzene, and toluene. It is soluble in dimethyl formamide and dimethyl sulfoxide. It is so purified and dried that:

(i) Its potency is not less than 750 micrograms of amphotericin B per milligram on an anhydrous basis.

(ii) It contains not more than 15 percent of amphotericin A.

(iii) It is nontoxic.

(iv) Its moisture content is not more than 5.0 percent.

(v) Its pH in a 3 percent aqueous suspension is not less than 6.0 and not more than 8.0.

(vi) It contains not more than 3.0 percent residue on ignition.

(vii) It exhibits absorption maxima at 362, 381, and 405 millimicrons when dissolved in dimethyl sulfoxide and diluted with absolute methyl alcohol.

(2) *Labeling.* In addition to the labeling prescribed by § 148.3(b) of this chapter, each package shall bear on its label the statements "Store below 10° C." and "Protect from light and moisture." Its expiration date is 12 months.

(3) *Request for certification.* In addition to the requirements of § 148.4 of this chapter, each such request shall contain:

(i) Results of tests and assays on the batch for potency, amphotericin A content, toxicity, moisture, pH, residue on ignition, and identity.

(ii) Samples required on the batch: 10 packages, each containing not less than 500 milligrams.

(4) *Fees.* $4.00 for each package in the sample submitted in accordance with subparagraph (3)(ii) of this paragraph.

(b) *Tests and methods of assay*—(1) *Potency*—(i) *Plate assay*—(*a*) *Cylinders (cups).* Use cylinders described in § 141a.1 of this chapter.

(*b*) *Culture media.* Use ingredients that conform to the standards, if any, prescribed by the U.S.P. or N.F.

(*1*) Make nutrient agar for preparing the inoculated agar plates as follows:

Peptone	9.4 gm.
Yeast extract	4.7 gm.
Beef extract	2.4 gm.
Sodium chloride	10.0 gm.
Dextrose	10.0 gm.
Agar	23.5 gm.
Distilled water, q.s.	1,000.0 ml.

pH 6.0 to 6.2 after sterilization.

(*2*) Make nutrient agar for carrying the organism as follows:

Peptone	6.0 gm.
Pancreatic digest of casein	4.0 gm.
Yeast extract	3.0 gm.
Beef extract	1.5 gm.
Dextrose	1.0 gm.
Agar	15.0 gm.
Distilled water, q.s.	1,000.0 ml.

pH 6.5 to 6.6 after sterilization.

(*3*) Make nutrient broth for preparing an inoculum of the test organism:

Peptone	10.0 gm.
Dextrose	20.0 gm.
Distilled water, q.s.	1,000.0 ml.

pH 5.6 to 5.7 after sterilization.

In lieu of preparing the media from the individual ingredients as specified, they may be prepared from a dehydrated mixture which, when reconstituted with distilled water, has the same composition as such media. Minor modifications of the specified individual ingredients are permissible if the resulting media possess growth-promoting properties at least equal to the media described.

(*c*) *Working standard.* Dry approximately 30 milligrams of the amphotericin B working standard for 3 hours at 60° C. and a pressure of 5 millimeters or less. Determine the dry weight, and dissolve the dried standard in sufficient dimethyl sulfoxide to give a stock solution containing 1,000 micrograms of amphotericin B per milliliter. This solution should be used for 1 day only.

(*d*) *Preparation of sample.* Dissolve the sample in sufficient dimethyl sulfoxide to give a convenient stock solution. Further dilute with dimethyl sulfoxide to a concentration of 20 micrograms of amphotericin B per milliliter (estimated). Remove an aliquot and dilute to a concentration of 1.0 microgram of amphotericin B per milliliter (estimated) using 0.2*M* potassium phosphate buffer, pH 10.5 (dipotassium phosphate, 35 grams; 10*N* sodium hydroxide, 2 milliliters). Make to 1 liter, using distilled water.

(*e*) *Test organism.* The test organism is Saccharomyces cerevisiae (ATCC 9763 or ATCC 2601 no vitamin requirement), which is maintained on slants of agar described in subsection (*b*)(*2*) of this subdivision and transferred once a week. After transfer, the culture is incubated at 37° C. for 24 hours and then kept refrigerated. Prepare the organism suspension by either of the following methods:

(*1*) Inoculate 100 milliliters of the broth medium described under subsection (*b*)(*3*) of this subdivision with a loopful of growth from the agar slant. Incubate the broth for 16 hours to 18 hours at 37° C. This broth culture may be used for several weeks if kept refrigerated.

(*2*) Wash the organism from the agar slant with 3 milliliters of sterile distilled water onto a large agar surface such as that provided by a Roux bottle containing 300 milliliters of the agar described in subsection (*b*)(*2*) of this subdivision. Spread the suspension of organisms over the entire agar surface with the aid of sterile glass beads. Incubate for 24 hours at 37° C., and then wash the resulting growth from the agar surface with about 30 milliliters of sterile distilled water. This suspension may be used for several weeks if kept refrigerated. Dilute an aliquot of the bulk suspension 1:45 with sterile distilled water and measure its light transmission in a suitable photoelectric colorimeter with a 580-millimicron filter and a test tube with an inside diameter of 13 millimeters, as an absorption cell. The bulk suspension is ready for use when an aliquot diluted 1:45 gives a light transmission of 25 percent. If necessary, adjust the bulk suspension by dilution until an aliquot diluted 1:45 gives 25 percent light transmission. At the time of inoculation dilute the adjusted bulk suspension 1:10 with sterile distilled water. Employ test plates to determine the quantity of this diluted suspension (usually about 0.7 milliliter) that should be added to each 100 milliliters of agar to give clear inhibitory zones of appropriate size. If the broth culture is used, employ test plates similarly (usually about 2.5 milliliters per 100 milliliters of agar).

(*f*) *Preparation of plates.* Melt a sufficient amount of the agar described in subsection (*b*)(*1*) of this subdivision, cool to 48° C., add the proper amount of the test organism as described in subsection (*e*) of this subdivision, and mix thoroughly. Add 8 milliliters of this inoculated agar to each Petri dish (100 millimeters x 20 millimeters, with flat bottom). Distribute the agar evenly in the plates, cover with porcelain covers glazed on the outside, and allow to harden. After the agar has hardened, place 6 cylinders on the agar surface so that they are at approximately 60° intervals on a 2.8-centimeter radius.

(*g*) *Standard curve.* Dilute aliquots of the working stock solution with dimethyl sulfoxide to give concentrations of 40.0, 28.4, 20.0, 14.2, and 10.0 micrograms per milliliter, respectively. Dilute one volume of each of these solutions with 19 volumes of 0.2*M* potassium phosphate buffer, pH 10.5, to give final concentrations of 2.0, 1.42, 1.0, 0.71, and 0.5 microgram per milliliter. A total of 12 plates is used in the preparation of the standard curve, three plates for each solution, except the 1.0 microgram per milliliter solution. The latter concentration is used as the reference point and is included on each plate. On each of the three plates fill three cylinders with the 1.0 microgram per milliliter standard and the other three cylinders with the concentration of the standard concentration under test. Thus, there will be thirty-six 1.0-microgram determinations and nine determinations for each of the other concentrations on the curve. Incubate the plates for 16 hours to 18 hours at 37° C., and measure the diameter of each zone of inhibition. Average the readings of the 1.0 microgram per milliliter concentration and the readings of the concentration tested for each set of three plates, and average also all 36 readings of the 1.0 microgram per milliliter concentration. The average of the 36 readings of the 1.0 microgram per milliliter concentration is the correction point for the curve. Correct the average value obtained for each point to the figure it would be if the 1.0 microgram per milliliter reading for that set of three plates were the same as the correction point. Thus, if in correcting the 0.71 microgram per milliliter concentration the average of the 36 readings of the 1.0 microgram per milliliter concentration is 16.0 millimeters and the average of the 1.0 microgram per milliliter concentration of this set of three plates is 15.8 millimeters, the correction is +0.2 millimeter. If the average reading of the 0.71 microgram per milliliter concentration of these same three plates is 15.0 millimeters, the corrected value is then 15.2 millimeters. Plot these corrected values, including the average of the 1.0 microgram per milliliter concentration on two-cycle semilog paper, using the concentration in micrograms per milliliter as the ordinate (the logarithmic scale) and the diameter of the zone of inhibition as the abscissa. Draw the standard curve through these points, either by inspection or by means of the following equations:

$$L=\frac{3a+2b+c-e}{5},$$

$$H=\frac{3e+2d+c-a}{5},$$

where:

L=Calculated zone diameter for the lowest concentration of the standard curve;

H=Calculated zone diameter for the highest concentration of the standard curve;

c=Average zone diameter for the 36 readings of the 1 microgram per milliliter standard;

a, b, d, e=Corrected zone diameters for the 0.5, 0.71, 1.42, and 2.0 microgram per milliliter solutions, respectively.

(*h*) *Assay*. Use three plates for each sample. Fill three cylinders on each plate with the 1.0 microgram per milliliter standard and three cylinders with the 1.0 microgram per milliliter (estimated) sample, alternating standard and sample. Incubate the plates for 16 hours to 18 hours at 37° C., and then measure the diameter of each zone of inhibition. To estimate the potency of the sample, average the zone readings of the standard and the zone readings of the sample on the three plates used. If the sample gives a larger zone size than the average of the standard, add the difference between them to the 1.0 microgram per milliliter zone on the standard curve. If the average value is lower than the standard value, subtract the difference between them from the 1.0 microgram per milliliter value on the curve. From the curves read the potencies corresponding to these corrected values of zone sizes.

(ii) *Turbidimetric assay*—(a) *Culture media*. Use ingredients that conform to the standards, if any, prescribed by the U.S.P. or N.F.

(*1*) Make yeast-beef agar for carrying the organism as follows:

Peptone	6.0 gm.
Yeast extract	3.0 gm.
Beef extract	1.5 gm.
Dextrose	1.0 gm.
Agar	15.0 gm.
Distilled water to make	1,000.0 ml.

pH 6.6 after sterilization.

(*2*) Make yeast-beef broth for preparing an inoculum of the test organism:

Beef extract	1.5 gm.
Yeast extract	6.5 gm.
Peptone	5.0 gm.
Trypton	10.0 gm.
Dextrose	11.0 gm.
Sodium chloride	3.5 gm.
Dipotassium phosphate	3.68 gm.
Monopotassium phosphate	1.32 gm.
Distilled water to make	1,000.0 ml.

pH 6.6 after sterilization.

(*3*) Make yeast-beef assay broth:

Beef extract	1.5 gm.
Yeast extract	1.5 gm.
Peptone	5.0 gm.
Dextrose	11.0 gm.
Sodium chloride	3.5 gm.
Dipotassium phosphate	3.68 gm.
Monopotassium phosphate	1.32 gm.
Distilled water to make	1,000.0 ml.

pH 6.6 after sterilization.

In lieu of preparing the media from the individual ingredients as specified, they may be prepared from a dehydrated mixture which, when reconstituted with distilled water, has the same composition as such media. Minor modifications of the specified individual ingredients are permissible if the resulting media possess growth-promoting properties at least equal to the media described.

(*b*) *Working standard and standard solutions*. Use the working standard described in subdivision (i) (*c*) of this subparagraph. Dissolve in dimethyl sulfoxide to obtain a concentration of 2 milligrams per milliliter. Further dilute to obtain a concentration of 30 micrograms per milliliter, using 25 percent dimethyl sulfoxide (one part dimethyl sulfoxide plus three parts distilled water). Use 1 percent potassium phosphate buffer, pH 6.0, and dilute to a concentration of 1 microgram per milliliter. Further dilute this solution with distilled water, and prepare the standard curve containing concentrations of 0.032, 0.04, 0.05, 0.0625, and 0.0781 microgram per milliliter. Add 1.0 milliliter of each concentration to each of six sterile 20 millimeters x 150 millimeters test tubes.

(*c*) *Preparation of sample*. Prepare the sample to be tested, using the same procedure as described for the standard solutions, obtaining six tubes each containing 1.0 milliliter of a solution containing 0.05 microgram per milliliter (estimated).

(*d*) *Preparation of test organism*. The test organism is Candida tropicalis (ATCC 13803), which is maintained on slants of agar described in (*a*) (*1*) of this subdivision. Prepare the daily inoculum by transferring the culture from a stock slant to 100 milliliters of the broth described in (*a*) (*2*) of this subdivision, and incubate for 16 hours to 18 hours at 30° C., with constant shaking. Prepare the daily inoculated assay broth by adding from 3 milliliters to 5 milliliters of a fresh 16 hour to 18 hour broth culture to each liter of assay broth, prepared as directed in (*a*) (*3*) of this subdivision, needed for the test.

(*e*) *Procedure*. To each of the 20 millimeters x 150 millimeters test tubes prepared in (*b*) and (*c*) of this subdivision, add 9.0 milliliters of the inoculated assay broth described in subsection (*d*) of this subdivision, and incubate all standard and sample tubes at 30° C., with constant shaking, for 3 to 5 hours. After incubation, add 0.5 milliliter of a 12 percent formaldehyde solution to each tube, and read the absorbance values in a suitable photoelectric colorimeter, using a wavelength of 530 millimicrons. Set the instrument at zero absorbance with clear uninoculated broth prepared as described in (*a*) (*3*) of this subdivision.

(*f*) *Estimation of potency*. Plot the average values for each concentration of the standard on semilog graph paper with absorbance values on the arithmetic scale and amphotericin concentrations on the logarithmic scale. Construct the best straight line through the points, either by inspection or by means of the following equations:

$$L=\frac{3a+2b+c-e}{5},$$

$$H=\frac{3e+2d+c-a}{5},$$

where:

L=Calculated absorbance value for the lowest concentration of the standard curve;

H=Calculated absorbance value for the highest concentration of the standard curve;

a, b, c, d, e=Average absorbance values for each concentration of the standard curve.

Plot the values obtained for L and H and connect the points with a straight line. Average the absorbance values for the sample and read the amphotericin concentration from the standard curve. Multiply the concentration by appropriate dilution factors to obtain the amphotericin content of the sample.

(2) *Amphotericin A content*—(i) *Amphotericin A*. Accurately weigh about 20 milligrams of the amphotericin A working standard into a 200-milliliter volumetric flask. Add exactly 20.0 milliliters of dimethyl sulfoxide and dissolve. Make to mark with methyl alcohol, and mix thoroughly. Pipette 4.0 milliliters of this solution into a 50-milliliter volumetric flask. Add methyl alcohol to mark, and mix thoroughly.

(ii) *Amphotericin B*. Accurately weigh about 50 milligrams of the amphotericin B working standard into a 50-

milliliter volumetric flask and proceed as directed in subdivision (i) of this subparagraph.

(iii) *Sample.* Accurately weigh about 50 milligrams of the sample to be tested, and proceed as directed in subdivision (i) of this subparagraph. The standards should be used for 1 day only.

(iv) *Blank.* Pipette 5.0 milliliters of dimethyl sulfoxide into a 50-milliliter volumetric flask. Make to mark with methyl alcohol, and mix. Pipette 4.0 milliliters of this solution into a 50-milliliter volumetric flask. Make to mark with methyl alcohol, and mix thoroughly.

(v) *Procedure.* Use a suitable ultraviolet spectrophotometer and 1-centimeter silica cells. Adjust the instrument to zero with the blank solution. Measure the absorbances of the solutions of standard A, standard B, and the sample at 304 millimicrons and at 282 millimicrons. Calculate the absorptivity of each standard at both wavelengths:

Percent amphotericin A

$$= \frac{[(B \times S_2) - (b \times S_1)] \times 625}{\text{Weight of sample in grams} \times [(B \times a) - (B \times A)]},$$

where:

A = Absorptivity of amphotericin A standard at 282 millimicrons;

B = Absorptivity of amphotericin B standard at 282 millimicrons;

a = Absorptivity of amphotericin A standard at 304 millimicrons;

b = Absorptivity of amphotericin B standard at 304 millimicrons;

S_1 = Absorbance of sample at 282 millimicrons;

S_2 = Absorbance of sample at 304 millimicrons.

(3) *Toxicity.* Proceed as directed in § 141d.305(b) of this chapter, except administer to each of 5 mice, 0.4 milliliter of a suspension of the drug containing 50 milligrams per milliliter in 0.5 percent gum acacia solution.

(4) *Moisture.* Proceed as directed in § 141a.5(a) of this chapter.

(5) *pH.* Using a 3.0 percent aqueous suspension, proceed as directed in § 141a.5(b) of this chapter.

(6) *Residue on ignition.* Proceed as directed in § 141e.401(g) of this chapter.

(7) *Identity.* Accurately weigh 50.0 milligrams of the sample into a dry 50-milliliter volumetric flask. Add exactly 5 milliliters of dimethyl sulfoxide and dissolve. Make to mark with methyl alcohol, and mix thoroughly. Pipette 4 milliliters of this solution into a 50-milliliter volumetric flask. Add methyl alcohol to the mark, and mix thoroughly. The sample has absorption peaks at identical wavelengths with that of the standard (272, 282, 295, 362, 381, and 405 millimicrons).

§ 148b.2 Amphotericin B intravenous.

(a) *Requirements for certification*—(1) *Standards of identity, strength, quality, and purity.* Amphotericin B intravenous is a dry powder containing in each immediate container 50 milligrams of amphotericin B, 41 milligrams of sodium desoxycholate, and suitable buffering substances. It is sterile. It is nontoxic. It is nonpyrogenic. Its moisture content is not more than 8.0 percent. Its pH in an aqueous solution containing 10 milligrams of amphotericin B per milliliter is not less than 7.2 and not more than 8.0. The amphotericin B used conforms to the standards of § 148b.1(a)(1)(i), (ii), (v), (vi), and (vii), except that its amphotericin A content is not more than 5 percent and its residue on ignition is not more than 0.5 percent. Each other substance used, if its name is recognized in the U.S.P. or N.F., conforms to the standards prescribed therefor by such official compendium.

(2) *Labeling.* In addition to the labeling requirements prescribed by § 148.3 of this chapter, each package shall bear on its label and labeling the following statement: "For intravenous infusion in hospitals only." Its expiration date is 12 months.

(3) *Request for certification.* In addition to the requirements of § 148.4 of this chapter, each such request shall contain:

(i) Results of tests and assays on:

(*a*) The amphotericin B used in making the batch for potency, amphotericin A content, pH, residue on ignition, and identity.

(*b*) The batch for potency, sterility, toxicity, pyrogens, moisture, and pH.

(ii) Samples required:

(*a*) Amphotericin B used in making the batch: 10 packages, each containing approximately equal portions of not less than 500 milligrams.

(*b*) The batch:

(*1*) For all tests except sterility: A minimum of 10 immediate containers.

(*2*) For sterility testing: 10 immediate containers.

(*c*) In case of an initial request for certification, each other ingredient used in making the batch: One package of each containing approximately 5 grams.

(4) *Fees.* $4.00 for each package in the samples submitted in accordance with subparagraph (3)(ii)(*a*) and (*c*) of this paragraph; $5.00 for each container in the sample submitted in accordance with subparagraph (3)(ii)(*b*)(*1*) of this paragraph; $10.00 for all immediate containers in the sample submitted in accordance with subparagraph (3)(ii)(*b*)(*2*) of this paragraph.

(b) *Tests and methods of assay*—(1) *Potency.* Dilute the sample in sufficient dimethyl sulfoxide to give a convenient stock solution, and proceed as directed in § 148b.1(b)(1). The amphotericin B content is satisfactory if it contains not less than 90 percent and not more than 120 percent of the number of milligrams of amphotericin B that it is represented to contain.

(2) *Sterility.* Proceed as directed in § 141a.2 of this chapter, using the entire contents of each container tested, except that neither penicillinase nor the control tube is used in the test for bacteria and except that the Sabouraud medium is adjusted to pH 7.5–7.9 with sodium hydroxide.

(3) *Toxicity.* Proceed as directed in § 141a.4 of this chapter, using a test dose of 0.3 milliliter of an aqueous solution containing 50 micrograms of amphotericin B per milliliter.

(4) *Pyrogens.* Proceed as directed in § 141a.3 of this chapter using as a test dose 0.5 milliliter per kilogram of a solution in sterile, pyrogen-free distilled water containing 2 milligrams of amphotericin B per milliliter. If no rabbit shows an individual rise in temperature of 1.1° C. or more above its respective control temperature, and if the sum of the three temperature rises does not exceed 3° C., the sample meets the requirements for absence of pyrogen. If one or two rabbits show a temperature rise of 1.1° C. or more, or if the sum of temperature rises exceeds 3° C., repeat the test using five other rabbits. If not more than three of the eight rabbits show a temperature rise of 1.1° C. or more, and if the sum of the temperature rises does not exceed 8° C. the sample meets the requirements for absence of pyrogens.

(5) *Moisture.* Proceed as directed in § 141a.5(a) of this chapter.

(6) *pH.* Proceed as directed in § 141a.5(b) of this chapter using an aqueous solution containing 10 milligrams of amphotericin B per milliliter.

PART 148c—COLISTIN

Sec.
148c.1 Colistin sulfate.
148c.2 Colistin sulfate-neomycin sulfate-thonzonium bromide-hydrocortisone acetate otic suspension.
148c.3 Colistin sulfate for oral suspension.
148c.4 Sodium colistimethate.

AUTHORITY: The provisions of this Part 148c issued under sec. 507, 59 Stat. 463, as amended 76 Stat. 785, 786, 787; 21 U.S.C.A. 357.

§ 148c.1 Colistin sulfate.

(a) *Requirements for certification*—(1) *Standards of identity, strength, quality, and purity.* Colistin sulfate is the white to slightly yellow, odorless sulfate salt of a kind of colistin or a mixture of two or more such salts. It is so purified and dried that:

(i) Its potency is not less than 500 micrograms of colistin per milligram.

(ii) It is nontoxic.

(iii) Its moisture content is not more than 7.0 percent.

(iv) Its pH in an aqueous solution containing 10 milligrams per milliliter is not less than 4.0 and not more than 7.0.

(v) It gives a positive identity test for colistin.

(2) *Labeling.* It shall be labeled in accordance with the requirements of § 148.3(b). Its expiration date is 12 months.

(3) *Request for certification.* In addition to the requirements of § 148.4, of this chapter, each such request shall contain:

(i) Results of tests and assays on the batch for potency, toxicity, moisture, pH, and identity.

(ii) Samples required on the batch: 10 packages, each containing approximately 300 milligrams.

(4) *Fees.* $4.00 for each immediate container in the sample submitted in accordance with subparagraph (3)(ii) of this paragraph.

(b) *Tests and methods of assay*—(1) *Potency*—(i) *Cylinders (cups).* Use cylinders described in § 141a.1(a) of this chapter.

(ii) *Culture media.* Use ingredients that conform to the standards prescribed by the U.S.P. or N.F.

(*a*) Nutrient agar for the base layer and for preparing the inoculated agar plates as follows:

	Base layer	Seed layer
Pancreatic digest of casein	17.0 gm.	17.0 gm.
Papaic digest of soybean	3.0 gm.	3.0 gm.
Sodium chloride	5.0 gm.	5.0 gm.
Dextrose	2.5 gm.	2.5 gm.
Dibasic potassium phosphate	2.5 gm.	2.5 gm.
Polysorbate 80	------	10.0 ml.
Agar	20.0 gm.	12.0 gm.
Distilled water to make	1,000.0 ml.	1,000.0 ml.
Final pH (after sterilization)	7.2–7.3	7.2–7.3

(*b*) Make nutrient agar for carrying the organism as follows:

Peptone	6.0 gm.
Pancreatic digest of casein	4.0 gm.
Yeast extract	3.0 gm.
Beef extract	1.5 gm.
Dextrose	1.0 gm.
Agar	15.0 gm.
Distilled water, q.s.	1,000.0 ml.

pH 6.5–6.6 after sterilization.

In lieu of preparing the medium from the individual ingredients specified, it can be made from a dehydrated mixture that, when reconstituted with distilled water, has the same composition as such medium. Minor modifications of the specified individual ingredients are permissible if the resulting medium possesses growth-promoting properties at least equal to the medium described.

(iii) *Preparation of test organism.* The test organism used is *Bordetella bronchiseptica* (ATCC 4617), which is maintained on slants of agar described in subdivision (ii)(*b*) of this subparagraph. Incubate the slants 24 hours at 37° C. Wash the organism from the slant with 3 milliliters of sterile U.S.P. saline T.S. onto a large agar surface such as provided by a Roux bottle containing 300 milliliters of the agar described in subdivision (ii)(*b*) of this subparagraph. Spread the suspension of organisms over the entire agar surface with the aid of sterile glass beads and incubate for 24 hours at 37° C. Wash the resulting growth with 50 milliliters of sterile U.S.P. saline T.S. and standardize the organism suspension so that a 1:20 dilution in U.S.P. saline T.S. will give 25 percent light transmission, using a filter having a wavelength of 580 millimicrons and test tube with an inside diameter of 13 millimeters as an absorption cell. Use test plates to determine the quantity (usually 0.3 milliliter) of this standardized bacterial suspension (not the 1:20 dilution) that should be added to each 100 milliliters of melted seed layer agar (cooled to 48° C–50° C.) to give clear, sharp, inhibition zones of appropriate diameter.

(iv) *Preparation of plates.* Use plates the same day they are prepared. Evenly distribute 21.0 milliliters of the melted base layer agar on each Petri dish (20 millimeters x 100 millimeters); cover with porcelain tops, glazed on the outside, and allow the agar to harden. Evenly spread 4.0 milliliters of the inoculated seed layer agar over the surface of the plate. After the seed layer has hardened, place six cylinders on the inoculated agar surface so that they are at approximately 60° intervals on a 2.8-centimeter radius.

(v) *Working standard.* Dry an appropriate amount of the working standard for 3 hours at 60° C. and a pressure of 5 millimeters or less. Determine the dry weight and prepare a stock solution of 1,000 micrograms of colistin per milliliter by diluting this dried working standard with 2 milliliters of sterile distilled water and further diluting with 10 percent potassium phosphate buffer, pH 6.0.

(vi) *Standard curve.* Prepare concentrations for the standard curve by diluting the working standard stock solution (1,000 micrograms of colistin per milliliter) with sterile 10 percent potassium phosphate buffer, pH 6.0, to give final concentrations of 0.64, 0.80, 1.0, 1.25, and 1.56 micrograms per milliliter. A total of 12 plates is used in the preparation of the standard curve, three plates for each solution, except the 1.0 microgram per milliliter solution. The latter concentration is used as the reference point and is included on each plate. On each of the three plates fill three cylinders with the 1.0 microgram per milliliter standard and the other three cylinders with the concentration of the standard concentration under test. Thus, there will be 36 one-microgram determinations and nine determinations for each of the other concentrations on the curve. Incubate the plates for 16 hours to 18 hours at 37° C. and measure the diameter of each zone of inhibition. Average the readings of the 1.0 microgram per milliliter concentration and the readings of the concentration tested for each set of three plates, and average also all 36 readings of the 1.0 microgram per milliliter concentration. The average of the 36 readings of the 1.0 microgram per milliliter concentration is the correction point for the curve. Correct the average value obtained for each point to the figure it would be if the 1.0 microgram per milliliter reading for that set of three plates were the same as the correction point. Thus, if in correcting the 1.25 microgram per milliliter concentration the average of the 36 readings of the 1.0 microgram per milliliter concentration is 18.0 milliliters, and the average of the 1.0 microgram per milliliter concentration of this set of three plates is 17.8 millimeters, the correction is +0.2 millimeter. If the average reading of the 1.25 microgram per milliliter concentration of those same three plates is 19.6 millimeters, the corrected value is then 19.8 millimeters. Plot these corrected values, including the average of the 1.0 microgram per milliliter concentration, on two-cycle semilog paper, using the concentration in micrograms per milliliter as the ordinate (the logarithmic scale) and the diameter of the zone of inhibition as the abscissa. Draw the standard curve through these points, either by inspection or by means of the following equations:

$$L=\frac{3a+2b+c-e}{5},$$

$$H=\frac{3e+2d+c-a}{5},$$

where:

L=Calculated zone diameter for the lowest concentration of the standard curve;

H=Calculated zone diameter for the highest concentration of the standard curve;

c=Average zone diameter for the 36 readings of the 1.0 microgram per milliliter standard;

a, b, d, e=Corrected zone values for the 0.64, 0.80, 1.25, 1.56 microgram per milliliter concentrations respectively.

(vii) *Preparation of sample.* Dissolve an accurately weighed quantity of the sample in sufficient 10 percent potassium phosphate buffer, pH 6.0, to give a convenient stock solution. Further dilute in the same buffer to obtain an estimated concentration of 1.0 microgram per milliliter.

(viii) *Assay.* Use three plates for each sample. Fill three cylinders on each plate with the 1.0 microgram per milliliter standard and three cylinders with the 1.0 microgram per milliliter (estimated) sample, alternating standard and sample. Incubate the plates for 16 hours to 18 hours at 37° C. and then measure the diameter of each zone of inhibition. To estimate the potency of the sample, average the zone readings of the standard and the zone readings of the sample on the three plates used. If the sample gives a larger zone size than the average of the standard, add the difference between them to the 1.0 microgram per milliliter zone on the standard curve. If the average value is lower than the standard value, subtract the difference between them from the 1.0 microgram per milliliter value on the curve. From the curve, read the potencies corresponding to these corrected values of zone sizes.

(2) *Toxicity.* Proceed as directed in § 141a.4 of this chapter, administering a 0.5 milliliter oral test dose of a suspension in sterile distilled water containing 600 micrograms of colistin per milliliter.

(3) *Moisture.* Proceed as directed in § 141a.5(a) of this chapter, using a sample of about 300 milligrams.

(4) *pH.* Proceed as directed in § 141a.5(b) of this chapter, using an aqueous solution containing 10 milligrams per milliliter.

(5) *Identity.* Weight about 20 milligrams of sample, add 2 milliliters of 2.5 percent sodium acetate solution and 0.2 milliliter of 0.5 percent triketohydrindene hydrate solution, and bring to boil. A deep-purple color results.

§ 148c.2 Colistin sulfate-neomycin sulfate-thonzonium bromide-hydrocortisone acetate otic suspension.

(a) *Requirements for certification*—(1) *Standards of identity, strength, quality, and purity.* Colistin sulfate-neomycin sulfate-thonzonium bromide-hydrocortisone acetate otic suspension is a suspension containing colistin sulfate, neomycin sulfate, thonzonium bromide, and hydrocortisone acetate, and one or more preservatives, dispersing agents, and buffer substances. Each milliliter contains 3.0 milligrams of colistin, 3.3 milligrams of neomycin, 0.5 milligrams of thonzonium bromide, and 10 milligrams of hydrocortisone acetate. It is sterile. Its pH is not less than 4.8

and not more than 5.2. The colistin sulfate used conforms to the standards prescribed therefor by § 148c.1(a)(1), except for toxicity. The neomycin sulfate used conforms to the standards prescribed by § 148i.1(a)(1) (i), (v), (vi), and (vii) of this chapter. Each other substance used, if its name is recognized in the U.S.P. or N.F., conforms to the standards prescribed therefor by such official compendium.

(2) *Labeling.* It shall be labeled in accordance with the requirements of § 148.3 of this chapter. Its expiration date is 12 months.

(3) *Request for certification.* In addition to the requirements of § 141.4 of this chapter, each such request shall contain:

(i) Results of tests and assays on:

(*a*) The colistin sulfate used in making the batch for potency, moisture, pH, and identity.

(*b*) The neomycin sulfate used in making the batch for potency, moisture, pH, and identity.

(*c*) The batch for colistin content, neomycin content, sterility, and pH.

(ii) Samples required:

(*a*) The colistin sulfate used in making the batch: 10 packages, each containing approximately 300 milligrams.

(*b*) The neomycin sulfate used in making the batch: 10 packages, each containing approximately 300 milligrams.

(*c*) The batch:

(*1*) For all tests except sterility: A minimum of six immediate containers.

(*2*) For Sterility: 10 immediate containers.

(*d*) In case of an initial request for certification, each other ingredient used in making the batch: One package of each containing approximately 5 grams.

(4) *Fees.* $4.00 for each immediate container in the samples submitted in accordance with subparagraph (3)(ii) (*a*), (*b*), and (*d*) of this paragraph; $5.00 for each immediate container in the sample submitted in accordance with subparagraph (3)(ii)(*c*)(*1*) of this paragraph; $10.00 for all samples submitted in accordance with subparagraph (3)(ii)(*c*)(*2*) of this paragraph.

(b) *Tests and methods of assay*—(1) *Colistin content.* Proceed as directed in § 148c.1(b)(1), except prepare the sample as follows: Thoroughly mix the sample and transfer an accurately measured aliquot of the sample into a 100-milliliter volumetric flask. Fill the flask to mark with 10 percent potassium phosphate buffer, pH 6.0. Further dilute to the proper estimated concentration in 10 percent potassium phosphate buffer, pH 6.0. Its content of colistin is satisfactory if it is not less than 90 percent and not more than 125 percent of the number of milligrams of colistin per milliliter that it is represented to contain.

(2) *Neomycin content.* Proceed as directed in § 148i.1(b)(1) of this chapter, except prepare the sample as follows: Thoroughly mix the sample and transfer an accurately measured aliquot to a 100-milliliter volumetric flask. Fill to mark with 0.1*M* potassium phosphate buffer, pH 8.0 Further dilute to the proper estimated concentration in pH 8.0 buffer. Its content of neomycin is satisfactory if it is not less than 90 percent and not more than 125 percent of the number of milligrams of neomycin per milliliter that it is represented to contain.

(3) *Sterility.* Use 0.25 milliliter from each container tested and proceed as directed in § 141a.2 of this chapter except that neither penicillinase nor the control tube is used in the test for bacteria.

(4) *pH.* Proceed as directed in § 141a.5(b) of this chapter, using the undiluted solution or suspension.

§ 148c.3 Colistin sulfate for oral suspension.

(a) *Requirements for certification*—(1) *Standards of identity, strength, quality, and purity.* Colistin sulfate for oral suspension is a dry mixture of colistin sulfate, with or without one or more suitable and harmless buffer substances, suspending and dispersing agents, diluents, colorings, and flavorings. The colistin sulfate content is 5.0 milligrams of colistin per milliliter of the reconstituted suspension. The moisture content is not more than 3.0 percent. The pH of the reconstituted suspension is not less than 5.0 and not more than 6.0. The colistin sulfate used conforms to the standards prescribed by § 148c.1(a)(1). Each other substance used, if its name is recognized in the U.S.P. or N.F., conforms to the standards prescribed therefor by such official compendium.

(2) *Labeling.* It shall be labeled as prescribed in § 148.3, of this chapter. Its expiration date is 12 months.

(3) *Request for certification.* In addition to the requirements of § 148.4 of this chapter, each such request shall contain:

(i) Results of tests and assays on:

(*a*) The colistin sulfate used in making the batch for potency, toxicity, moisture, pH, and identity.

(*b*) The batch for potency, moisture, and pH.

(ii) Samples required:

(*a*) The colistin sulfate used in making the batch: 10 packages, each containing approximately 300 milligrams.

(*b*) The batch: A minimum of 6 immediate containers.

(*c*) In case of an initial request for certification, each other ingredient used in making the batch: One package of each containing not less than approximately 5 grams.

(4) *Fees.* $4.00 for each container submitted in accordance with subparagraph (3)(ii) of this paragraph.

(b) *Tests and methods of assay*—(1) *Potency.* Proceed as directed in § 148c.1 (b)(1), except prepare the sample as follows: Reconstitute the suspension as directed in the label. Remove a single-dose aliquot of the reconstituted suspension with a syringe and dilute in 1.0 percent potassium phosphate buffer, pH 6.0. The colistin content is satisfactory if it contains not less than 90 percent and not more than 120 percent of the number of milligrams of colistin that it is represented to contain.

(2) *Moisture.* Proceed as directed in § 141a.5(a) of this chapter.

(3) *pH.* Proceed as directed in § 141a.5 of this chapter, using the suspension when reconstituted as directed in the labeling.

§ 148c.4 Sodium colistimethate.

(a) *Requirements for certification*—(1) *Standards of identity, strength, quality, and purity.* Sodium colistimethate is the sodium salt of a kind of colistin methane sulfonate or a mixture of two or more such salts. It is a white to slightly yellow, odorless, fine powder which is freely soluble in water. It is so purified and dried that:

(i) Its potency is not less than 300 micrograms of colistin base per milligram.

(ii) It is sterile.

(iii) It is nontoxic.

(iv) It is nonpyrogenic.

(v) It contains no histamine nor histamine-like substances.

(vi) Its moisture content is not more than 9.0 percent.

(vii) Its pH in an aqueous solution contains 10 milligrams per milliliter is not less than 6.5 and not more than 9.0.

(viii) It gives a positive identity test for sodium colistimethate.

(ix) Its heavy metals content is not more than 30 parts per million.

(2) *Labeling.* It shall be labeled in accordance with the requirements of § 148.3 of this chapter. Its expiration date is 12 months.

(3) *Request for certification.* In addition to the requirements of § 148.4 of this chapter, each such request shall contain:

(i) Results of tests and assays on the batch for potency, sterility, toxicity, pyrogens, histamine, moisture, pH, identity, and heavy metals.

(ii) Samples required:

(*a*) For all tests except sterility: 10 containers, each containing not less than 500 milligrams.

(*b*) For sterility testing: 10 packages, each containing approximately 500 milligrams.

(4) *Fees.* $5.00 for each container in the sample submitted in accordance with subparagraph (3)(ii)(*a*) of this paragraph; $10.00 for all containers submitted in accordance with subparagraph (3)(ii)(*b*) of this paragraph.

(b) *Tests and methods of assay*—(1) *Potency.* Proceed as directed in § 148c.1 (b)(1) except use the sodium colistimethate working standard the same day it is prepared.

(2) *Sterility.* Use the entire contents of a container or the equivalent of approximately 500 milligrams of colistin from each large container and proceed as directed in § 141a.2 of this chapter, except that neither penicillinase nor the control tube is used in the test for bacteria.

(3) *Pyrogens.* Proceed as directed in § 141a.3 of this chapter, using a test dose of 1.0 milliliter per kilogram of a solution in sterile, pyrogen-free distilled water, containing 10 milligrams of colistin per milliliter.

(4) *Toxicity.* Proceed as directed in § 141a.4 of this chapter, using a test dose of 0.5 milliliter of a solution in

sterile distilled water containing 1.5 milligrams of colistin per milliliter.

(5) *Histamine.* Proceed as directed in § 141b.105 of this chapter, using a test dose of 1 milliliter per kilogram of a solution containing 3.0 milligrams of colistin per milliliter.

(6) *Moisture.* Proceed as directed in § 141a.5(a) of this chapter, using a sample of not less than 100 milligrams.

(7) *pH.* Proceed as directed in § 141a.5 (b) of this chapter, using a 1 percent aqueous solution prepared in the following manner: Weigh accurately 0.5 gram of sample and transfer to a 125-milliliter Erlenmeyer flask. Add 50 milliliters of freshly boiled distilled water, stopper, and shake until the sample is in solution. Allow to stand for one-half hour before determining the pH.

(8) *Identity.* To about 20 milligrams of sample add 2 milliliters of 2.5 percent sodium acetate solution and 0.2 milliliter of 0.5 percent triketohydrindene hydrate solution. Bring to boil. No pink color results. To about 20 milligrams of sample add 2 milliliters of dilute hydrochloric acid. Reflux for about 2 minutes, neutralize with 10 percent sodium hydroxide, and add sodium acetate. A deep-purple color results.

(9) *Heavy metals.* Proceed as directed in § 148m.1(b)(9) of this chapter.

PART 148d—CYCLOSERINE

Sec.

148d.1 Cycloserine.
148d.2 Cycloserine capsules.
148d.3 Cycloserine capsules with isoniazid.

AUTHORITY: The provisions of this Part 148d issued under sec. 507, 59 Stat. 463, as amended 76 Stat. 785, 786, 787; 21 U.S.C.A. 357.

§ 148d.1 Cycloserine.

(a) *Requirements for certification* —(1) *Standards of identity, strength, quality, and purity.* Cycloserine is a white to slightly yellowish crystalline compound. It has the chemical structure D-4-amino-3-isoxazolidone. It is so purified that:

(i) Its potency is not less than 900 micrograms per milligram.

(ii) It is nontoxic.

(iii) Its moisture content is not more than 1.0 percent.

(iv) Its pH in a 10 percent aqueous solution is not less than 5.5 and not more than 6.5.

(v) Its residue on ignition is not more than 0.5 percent.

(vi) It gives a positive identity for cycloserine.

(2) *Labeling.* It shall be labeled in accordance with the requirements of § 148.3(b) of this chapter. Its expiration date is 12 months.

(3) *Request for certification.* In addition to the requirements of § 148.4 of this chapter, each such request shall contain:

(i) Results of tests and assays on the batch for potency, toxicity, moisture, pH, residue on ignition, crystallinity, and identity.

(ii) Samples of the batch: 10 packages, each containing approximately 500 milligrams.

(4) *Fees.* $4.00 for each container in the sample submitted in accordance with subparagraph (3)(ii) of this paragraph.

(b) *Tests and methods of assay*—(1) *Potency*—(i) *Colorimetric assay*—(*a*) *Stock standard solution.* Dry approximately 100 milligrams of the working standard for 3 hours at 60° C. and a pressure of 5 millimeters or less. Determine the dry weight and dissolve the dried working standard in sufficient 0.1*N* sodium hydroxide to give a solution containing 1,000 micrograms per milliliter.

(*b*) *Standard curve solutions.* Pipette accurately 0.0, 1.0, 5.0, 10.0, 15.0, and 20.0 milliliters of the stock standard solution to each of six 100-milliliter volumetric flasks, dilute to 100 milliliters with 0.1*N* sodium hydroxide and mix thoroughly.

(*c*) Reagents:

(*1*) Acetic acid—1.0*N* solution.

(*2*) Sodium hydroxide—4.0*N* and 0.1*N* solutions.

(*3*) Sodium nitroprusside—4.0 percent solution: Dissolve 4.0 grams in sufficient distilled water to make 100.0 milliliters. Mix well. Store in amber bottle.

(*4*) Oxidized nitroprusside reagent—Mix equal parts of 4 percent sodium nitroprusside solution and 4.0*N* sodium hydroxide, and let stand for 1 hour before using. Prepare daily, and store in an amber bottle.

(*d*) *Procedure.* Transfer approximately 100 milligrams of sample, accurately weighed, to a 100-milliliter volumetric flask. Dissolve in sufficient 0.1*N* sodium hydroxide to measure exactly 100 milliliters. Mix thoroughly and transfer 10 milliliters to a second 100-milliliter volumetric flask, and mix thoroughly. Transfer exactly 1.0 milliliter of each of the standard curve solutions and of the sample solution to respective test tubes. Add exactly 3.0 milliliters of 1.0*N* acetic acid to each of the test tubes. Mix thoroughly. Add exactly 1.0 milliliter of oxidized nitroprusside reagent to each test tube and mix thoroughly. Allow the tubes to stand at room temperature for at least 10 minutes in order that maximum color intensity may develop. Using the solution containing 0.0 milliliter of working standard as a blank, determine the absorbances of the solutions at 625 millimicrons in a suitable spectrophotometer. Plot concentration versus absorbance on linear graph paper. The curve may deviate slightly from a straight line. The standard curve solutions equal 0, 10, 50, 100, 150, and 200 micrograms of cycloserine, respectively.

(*e*) Calculations:

$$\text{Micrograms cycloserine per milligram} = \frac{\text{Concentration in micrograms from calibration curve} \times 1{,}000}{\text{Weight of original sample in milligrams}}.$$

(ii) *Plate assay*—(*a*) *Cylinders (cups).* Use cylinders described in § 141a.1(a) of this chapter.

(*b*) *Culture media.* Use ingredients that conform to the standards prescribed by the U.S.P. or N.F.

(*1*) Base layer agar:

Peptone	6.0 gm.
Yeast extract	3.0 gm.
Beef extract	1.5 gm.
Agar	15.0 gm.
Distilled water, q.s.	1,000.0 ml.

pH 6.5 to 6.6 after sterilization.

(*2*) Seed layer agar (also used for maintaining test organism):

Peptone	6.0 gm.
Pancreatic digest of casein	4.0 gm.
Yeast extract	3.0 gm.
Beef extract	1.5 gm.
Dextrose	1.0 gm.
Agar	15.0 gm.
Distilled water, q.s.	1,000.0 ml.

pH 6.5 to 6.6 after sterilization.

In lieu of preparing the medium from the individual ingredients specified, it can be made from a dehydrated mixture that, when reconstituted with distilled water, has the same composition as such medium. Minor modifications of the individual ingredients specified in subdivision (ii)(*b*) (*1*) and (*2*) of this subparagraph are permissible if the resulting media possess growth-promoting properties equal to the media described.

(*c*) *Preparation of test organism.* The test organism used is *Staphylococcus aureus* (ATCC 6538P). Incubate a seed agar slant that has been streaked with the organism, for 24 hours at 37° C. Wash the slant with 3 milliliters of sterile U.S.P. saline T.S. with the aid of glass beads onto a Roux bottle containing 300 milliliters of seed agar. Incubate for 24 hours at 37° C. and wash with 50 milliliters of sterile U.S.P. saline T.S. into an Erlenmeyer flask. Using a suitable photoelectric colorimeter with a filter having a wavelength of 580 millimicrons, and with a test tube having an inside diameter of 13 millimeters, as an absorption cell, adjust the suspension so that a 1:20 dilution with U.S.P. saline T.S. will give 25 percent light transmission. Determine by test plates the amount of inoculum to be added to the seed layer to obtain satisfactory zones (usually 2 percent of a 1:50 dilution).

(*d*) *Preparation of plates.* Use plates the same day they are prepared. Evenly distribute 10.0 milliliters of the melted base layer agar on each Petri dish (20 millimeters x 100 millimeters); cover with porcelain tops, glazed on the outside, and allow the agar to harden. Evenly spread 4.0 milliliters of the inoculated seed layer agar over the surface of the plate. After the seed layer has hardened, place six cylinders on the inoculated agar surface so that they are at approximately 60° intervals on a 2.8-centimeter radius.

(*e*) *Standard.* Dry an appropriate amount of the working standard for 3 hours at 60° C. with a pressure of 5 millimeters or less. Determine the dry weight and dissolve the dried working standard in sufficient distilled water to obtain a stock solution of 1,000 micrograms per milliliter. This solution may be used for 2 days if kept under refrigeration.

(*f*) *Standard curve.* Prepare concentrations for the standard curve by diluting the working standard stock solution (1,000 micrograms per milliliter) in 1 percent potassium phosphate buffer, pH 6.0, to give final concentrations of 32, 40, 50, 62.5, and 78.1 micrograms per milliliter. A total of 12 plates is used in the preparation of the standard curve, three plates for each solution, except the 50 micrograms per milliliter solution. The latter concentration is used as the reference point and is included on each plate. On each of the three plates fill three cylinders with 50 micrograms per milliliter standard and the other three cylinders with the concentration of the standard concentration under test. Thus, there will be thirty-six 50-microgram determinations and nine determinations for each of the other concentrations on the curve. Incubate the plates for 16 hours to 18 hours at 30° C., and measure the diameter of each zone of inhibition. Average the readings of the 50 micrograms per milliliter concentration and the readings of the concentration tested for each set of three plates, and average also all 36 readings of the 50 micrograms per milliliter concentration. The average of the 36 readings of the 50 micrograms per milliliter concentration is the correction point for the curve. Correct the average value obtained for each point to the figure it would be if the 50 micrograms per milliliter reading for that set of three plates were the same as the correction point. Thus, if in correcting the 62.5 micrograms per milliliter concentration the average of the 36 readings of the 50 micrograms per milliliter concentration is 18.0 millimeters and the average of the 50 micrograms per milliliter concentration of this set of three plates is 17.8 millimeters, the correction is +0.2 millimeter. If the average reading of the 62.5 micrograms per milliliter concentration of those same three plates is 19.6 millimeters, the corrected value is then 19.8 millimeters. Plot these corrected values, including the average of the 50 micrograms per milliliter concentration, on two-cycle semilog paper, using the concentration in micrograms per milliliter as the ordinate (the logarithmic scale) and the diameter of the zone of inhibition as the abscissa. Draw the standard curve through these points, either by inspection or by means of the following equations:

$$L=\frac{3a+2b+c-e}{5},$$

$$H=\frac{3e+2d+c-a}{5},$$

where:

L=Calculated zone diameter for the lowest concentration of the standard;
H=Calculated zone diameter for the highest concentration of the standard;
c=Average zone diameter for the 50 micrograms per milliliter standard;
a, b, d, e=Corrected average value for the 32, 40, 62.5, and 78.1 microgram per milliliter standard solution, respectively.

(*g*) *Preparation of Sample.* Dissolve an accurately weighed quantity of the sample in 1 percent potassium phosphate buffer, pH 6.0, to an estimated concentration of 50 micrograms per milliliter.

(*h*) *Assay.* Use three plates for each sample. Fill three cylinders on each plate with the 50 micrograms per milliliter standard and three cylinders with the 50 micrograms per milliliter (estimated) sample, alternating standard and sample. Incubate the plates for 16 hours to 18 hours at 30° C. and then measure the diameter of each zone of inhibition. To estimate the potency of the sample, average the zone readings of the standard and the zone readings of the sample on the three plates used. If the sample gives a larger zone size than the average of the standard, add the difference between them to the 50 micrograms per milliliter zone on the standard curve. If the average value is lower than the standard value, subtract the difference between them from the 50 micrograms per milliliter value on the curve. From the curves, read the potencies corresponding to these corrected values of zone sizes.

(2) *Toxicity.* Proceed as directed in § 141a.4 of this chapter, using a test dose of 0.5 milliliter of a solution in sterile U.S.P. saline T.S.

NOTE: Solution must be administered within ½-hour after preparation.

(3) *Moisture.* Proceed as directed in § 141a.5(a) of this chapter.

(4) *pH.* Proceed as directed in § 141a.5(b) of this chapter, using a solution with a concentration of 100 milligrams per milliliter.

(5) *Crystallinity.* Proceed as directed in § 141a.5(c) of this chapter.

(6) *Residue on ignition.* Proceed as directed in § 141e.401(g) of this chapter.

(7) *Identity.* Proceed as directed in subparagraph (1)(i) of this paragraph.

§ 148d.2 Cycloserine capsules.

(a) *Requirements for certification*—(1) *Standards of identity, strength, quality, and purity.* Cycloserine capsules are capsules composed of crystalline cycloserine, with or without one or more suitable and harmless buffer substances, diluents, binders, and lubricants. Each capsule contains 250 milligrams of cycloserine. The moisture content is not more than 1.0 percent. The cycloserine used conforms to the standards prescribed by § 148d.1(a)(1). Each other substance used, if its name is recognized in the U.S.P. or N.F., conforms to the standards prescribed therefor by such official compendium.

(2) *Labeling.* In addition to the labeling prescribed by § 148.3 of this chapter, the labeling of each package shall bear a warning to the effect that the drug is to be used in patients with tuberculosis who fail to respond to treatment with isoniazid, streptomycin, para-aminosalicylic acid, viomycin, pyrazinamide, or combinations of these drugs, and that the drug may cause serious reactions such as convulsive seizures and mental disturbances. Its expiration date is 12 months.

(3) *Request for certification.* In addition to the requirements of § 148.4 of this chapter, each such request shall contain:

(i) Results of tests and assays on:

(*a*) Cycloserine used in making the batch for potency, toxicity, pH, residue on ignition, crystallinity, and identity.

(*b*) The batch for cycloserine content and moisture.

(ii) Samples required:

(*a*) Cycloserine used in making the batch: 10 packages, each containing approximately 500 milligrams.

(*b*) The batch: Minimum of 30 capsules.

(*c*) In case of an initial request for certification, each other ingredient used in making the batch: One package of each, containing approximately 5 grams.

(4) *Fees.* $4.00 for each package in the samples submitted in accordance with subparagraph (3)(ii) (*a*) and (*c*) of this paragraph; $.75 for each capsule in the sample submitted in accordance with subparagraph (3)(ii)(*b*) of this paragraph.

(b) *Tests and methods of assay*—(1) *Potency*—(i) *Chemical colorimetric assay.* (*a*) Reagents:

(*1*) Acetic acid—1.0*N* solution.

(*2*) Sodium hydroxide—4.0*N* and 0.1*N* solutions.

(*3*) Sodium nitroprusside—4.0 percent solution: Dissolve 4.0 grams in sufficient distilled water to make 100.0 milliliters. Mix well. Store in amber bottle.

(*4*) Oxidized nitroprusside reagent—Mix equal parts of the 4.0 percent sodium nitroprusside solution and 4.0*N* sodium hydroxide, and let stand for 1 hour before using. Prepare daily, and store in amber bottle.

(*5*) Cycloserine standard solution—Prepare a standard solution of the cycloserine working standard in 0.1*N* sodium hydroxide to contain 100 micrograms per milliliter.

(*b*) *Procedure.* Transfer the contents of 10 capsules into a 1,000-milliliter volumetric flask. Add 0.1*N* sodium hydroxide to dissolve the sample, and add sufficient 0.1*N* sodium hydroxide to measure 1,000 milliliters. Mix well, and filter. Dilute an aliquot of the filtrate with sufficient 0.1*N* sodium hydroxide to give a concentration of 0.1 milligram per milliliter (estimated) and mix well. Pipette exactly 1.0 milliliter of the working standard solution and 1.0 milliliter of the sample solution into separate test tubes. Add exactly 3.0 milliliters of 1.0*N* acetic acid and exactly 1.0 milliliter of oxidized nitroprusside reagent to each of the test tubes; then mix thoroughly. Allow the tubes to stand at room temperature for 10 minutes–15 minutes, in order that maximum color intensity may develop. Using a reagent blank, determine the absorbance of the solutions at 625 millimicrons in a suitable spectrophotometer.

Calculation:

$$\text{Milligrams of cycloserine per capsule}=\frac{\text{Sample absorbance}}{\text{Standard absorbance}}\times\text{Labeled potency per capsule in milligrams.}$$

(ii) *Biological assay.* Using a high-speed blender, prepare an appropriate number of capsules in 500 milliliters of 1 percent potassium phosphate buffer, pH 6.0, and proceed as directed in § 148d.1(b)(1)(ii).

The average potency is satisfactory if it contains not less than 90 percent and not more than 120 percent of the number of milligrams of cycloserine that it is represented to contain.

(2) *Moisture.* Proceed as directed in § 141a.5(a) of this chapter.

§ 148d.3 Cycloserine capsules with isoniazid.

(a) *Requirements for certification*—(1) *Standards of identity, strength, quality, and purity.* Cycloserine capsules with isoniazid are capsules composed of crystalline cycloserine and isoniazid, with or without, one or more suitable and harmless buffer substances, diluents, binders, and lubricants. Each capsule contains 250 milligrams of cycloserine and 150 milligrams of isoniazid. The moisture content is not more than 1.0 percent. The cycloserine used conforms to the standards prescribed by § 148d.1(a)(1). Each other substance used, if its name is recognized in the U.S.P. or N.F., conforms to the standards prescribed therefor by such official compendium.

(2) *Labeling.* In addition to the labeling prescribed by § 148.3 of this chapter, the labeling of each package shall bear a warning to the effect that the drug is to be used in patients with tuberculosis who fail to respond to treatment with isoniazid, streptomycin, para-aminosalicyclic acid, viomycin, pyrazinamide, or combinations of these drugs and that the drug may cause serious reactions such as convulsive seizures and mental disturbances. Its expiration date is 12 months.

(3) *Request for certification.* In addition to the requirements of § 148.3 of this chapter, each such request shall contain:

(i) Results of tests and assays on:

(*a*) Cycloserine used in making the batch for potency, toxicity, pH, residue on ignition, crystallinity, and identity.

(*b*) The batch for cycloserine content, isoniazid content, and moisture.

(ii) Samples required:

(*a*) Cycloserine used in making the batch: 10 packages, each containing approximately 500 milligrams.

(*b*) The batch: Minimum of 30 capsules.

(*c*) In case of an initial request for certification, each other ingredient used in making the batch: One package of each containing approximately 5 grams.

(4) *Fees.* $4.00 for each package in the sample submitted in accordance with subparagraph (3)(ii) (*a*) and (*c*) of this paragraph; $1.00 for each capsule in the sample submitted in accordance with subparagraph (3)(ii)(*b*) of this paragraph.

(b) *Tests and methods of assay*—(1) *Potency*—(i) *Chemical assays for cycloserine and isoniazid*—(*a*) *Preparation of sample.* Transfer the entire contents of four representative capsules to a 1,000-milliliter volumetric flask. Dilute to volume with distilled water, and mix well. Filter about 30 milliliters of the solution, discarding the first few milliliters of filtrate. Collect the remaining filtrate. Transfer a 10.0-milliliter aliquot of the filtrate to a 1,000-milliliter volumetric flask, dilute to volume with 0.1*N* hydrochloric acid, and mix well.

(*b*) *Preparation of cycloserine standard.* Accurately weigh about 30 milligrams of the cycloserine working standard and dissolve in sufficient distilled water to give a concentration of 1.0 milligram per milliliter. Transfer a 10.0-milliliter aliquot of this solution to a 1,000-milliliter volumetric flask. Dilute to volume with 0.1*N* hydrochloric acid, and mix well.

(*c*) *Preparation of isoniazid standard.* Accurately weigh about 30 milligrams of pure isoniazid and dissolve in sufficient distilled water to give a concentration of 1.0 milligram per milliliter. Transfer a 10.0-milliliter aliquot of this solution to a 1,000-milliliter volumetric flask. Dilute to volume with 0.1*N* hydrochloric acid, and mix well.

(*d*) *Procedure.* Adjust a suitable ultraviolet spectrophotometer to 100 percent light transmission with 0.1*N* hydrochloric acid in the absorption cell. Determine the absorbance values for the sample, the cycloserine standard, and the isoniazid standard at the absorption peaks at 219 millimicrons and 268 millimicrons. If a recording spectrophotometer is used, record the ultraviolet absorption spectrum from 210 millimicrons to 290 millimicrons. If a nonrecording spectrophotometer is used, determine the absorbance values at the absorption peaks. (The exact position of the peaks should be determined for the particular instrument used.)

(*e*) *Calculations*—(*1*) Cycloserine content: Determine the ratio (*R*) of the absorbance of the isoniazid standard at 219 millimicrons to its absorbance at 268 millimicrons.

$$R=\frac{\text{Absorbance of isoniazid standard at 219 millimicrons}}{\text{Absorbance of isoniazid standard at 268 millimicrons}}$$

Correct the absorbance value of the sample at 219 millimicrons for the isoniazid equivalent as follows:

$$A_c=(A_1-A_2\times R),$$

where:

A_c=Corrected absorbance at 219 millimicrons;
A_1=Absorbance of sample at 219 millimicrons;
A_2=Absorbance of sample at 268 millimicrons.

Calculate the cycloserine content as follows:

$$\text{Milligrams of cycloserine per capsule}=\frac{A_c}{A_s}\times 250,$$

where:

A_s=Absorbance of cycloserine standard at 219 millimicrons.

The content of cycloserine is satisfactory if it contains not less than 90 percent and not more than 120 percent of the number of milligrams of cycloserine that it is represented to contain.

(*2*) *Isoniazid content*—(*i*) *Preparation of sample.* Use the solution prepared as directed in subdivision (i)(*a*) of this subparagraph.

(*ii*) *Preparation of standard.* Use the solution prepared as directed in subdivision (i)(*c*) of this subparagraph.

(*iii*) *Procedure.* Proceed as directed in subdivision (i)(*d*) of this subparagraph and obtain the absorbance of the sample and the isoniazid standard at the absorption peak at 268 millimicrons. Calculate as follows:

$$\text{Milligrams of isoniazid per capsule}=\frac{A_2\times 250}{A_1},$$

where:

A_1=Absorbance of isoniazid standard at 268 millimicrons;
A_2=Absorbance of sample at 268 millimicrons.

The content of isoniazid is satisfactory if it contains not less than 90 percent and not more than 120 percent of the number of milligrams that it is represented to contain.

(ii) *Plate assay method for cycloserine content.* Proceed as directed in § 148d.2(b)(1)(ii). The average content of cycloserine in each capsule is satisfactory if it contains not less than 90 percent and not more than 120 percent of the number of milligrams that each capsule is represented to contain.

(2) *Moisture.* Proceed as directed in § 141a.26(e) of this chapter.

PART 148f—GRAMICIDIN

§ 148f.1 Gramicidin.

(a) *Requirements for certification*—(1) *Standards of identity, strength, quality, and purity.* Gramicidin is the white, or nearly white, odorless, crystalline compound of a kind of gramicidin or a mixture of two or more such compounds. It is so purified and dried that:

(i) It has a potency of not less than 900 micrograms of gramicidin per milligram.

(ii) It is nontoxic.

(iii) Its moisture content is not more than 3 percent.

(iv) Its residue on ignition is not more than 1.0 percent.

(v) It does not melt below 229° C. after drying in vacuum at 60° C. for 3 hours.

(vi) The difference between the absorptivity value at the maximum occurring at 282 millimicrons and the absorptivity value at the minimum occurring at 247 millimicrons is 100±4 percent of the difference obtained with the gramicidin working standard.

(2) *Labeling.* It shall be labeled in accordance with the requirements of § 148.3(b) of this chapter. Its expiration date is 12 months.

(3) *Request for certification.* In addition to the requirements of § 148.4 of this chapter, each such request shall contain:

(i) Results of tests and assays on the batch for potency, toxicity, moisture, residue on ignition, melting point, identity, and crystallinity.

(ii) Samples required of the batch: Ten packages, each containing approximately 500 milligrams.

(4) *Fees.* $4.00 for each immediate container in the sample submitted in accordance with subparagraph (3)(ii) of this paragraph.

(b) *Tests and methods of assay*—(1) *Potency*—(i) *Culture medium.* Use ingredients that conform to the standards prescribed by the U.S.P. or N.F. Make nutrient broth for preparing an inoculum of the test organism, as follows:

Peptone	5.0 gm.
Yeast extract	1.5 gm.
Beef extract	1.5 gm.
Sodium chloride	3.5 gm.
Dextrose	1.0 gm.
Dipotassium phosphate	3.68 gm.
Potassium dihydrogen phosphate	1.32 gm.
Distilled water, q.s.	1,000.00 ml.

pH 7.0 after sterilization.

In lieu of preparing the medium from the individual ingredients specified above, the nutrient broth may be made from a dehydrated mixture that, when reconstituted with distilled water, has the same composition as such medium. Minor modifications of the individual ingredients specified are permissible if the resulting medium possesses growth-promoting properties at least equal to the medium described.

(ii) *Working standard.* Dry an appropriate amount of the gramicidin working standard for 3 hours at 60° C. and a pressure of 5 millimeters or less. Determine the dry weight and dissolve in sufficient 95 percent alcohol to obtain stock solution of 1,000 micrograms per milliliter. Keep this stock solution in the refrigerator. Do not use it later than 30 days after it is made.

(iii) *Preparation of sample.* Dissolve an appropriate quantity of the sample in a volume of 95 percent ethyl alcohol to obtain a convenient stock solution. Make further dilutions volumetrically in 95 percent ethyl alcohol to obtain a final concentration of 0.04 microgram per milliliter (estimated).

(iv) *Preparation of test organism.* The test organism is Streptococcus faecalis (ATCC 10541) which is maintained in 100-milliliter quantities of the nutrient broth described in subdivision (i) of this subparagraph. For the test, prepare a fresh subculture by transferring a loopful of the stock culture to 100 milliliters of nutrient broth, and incubate 16 hours to 18 hours at 37° C. For the daily inoculum, use 6.0 milliliters of the subculture for each 1,000 milliliters of nutrient broth needed in the assay.

(v) *Procedure.* Prepare solutions for the daily standard curve by diluting an aliquot of the stock working standard solution prepared as described in subdivision (ii) of this subparagraph in 95 percent ethyl alcohol to obtain concentrations of 0.028, 0.034, 0.040, 0.048, and 0.058 microgram per milliliter. Place 0.1 milliliter of each concentration of the standard curve and of the sample solution prepared as described in subdivision (iii) of this subparagraph in each of three replicate test tubes, 16 millimeters x 125 millimeters (outside dimensions). To each tube, add 9 milliliters of the inoculated broth described in subdivision (iv) of this subparagraph and place immediately in a water bath at 37° C. for 3 hours to 4 hours. Remove the tubes and add 0.5 milliliter of a 12 percent solution of formaldehyde to each tube. Read the absorbance values of each tube in a suitable photoelectric colorimeter, using a wavelength of 530 millimicrons. Set the instrument at zero absorbance with clear, uninoculated broth prepared as described in subdivision (i) of this subparagraph.

(vi) *Estimation of potency.* Plot the average absorbance values for each concentration of the standard on two-cycle semi-logarithmic graph paper with absorbance values on the arithmetic scale and concentrations on the logarithmic scale. Construct the best straight line through the points either by inspection or by means of the following equations:

$$L=\frac{3a+2b+c-e}{5},$$

$$H=\frac{3e+2d+c-a}{5},$$

where:

L=Calculated absorbance value for the lowest concentration of the curve;

H=Calculated absorbance value for the highest concentration of the standard curve;

a, b, c, d, e=Average absorbance values for each concentration of the standard curve.

Plot the values obtained for L and H and connect the points with a straight line. Average the absorbance value for the sample and read the gramicidin concentration from the standard curve. Multiply the concentration by appropriate dilution factors to obtain the gramicidin content of the sample.

(2) *Toxicity.* Proceed as directed in § 141a.4 of this chapter, except inject subcutaneously with 0.5 milliliter of a suspension of the sample containing 5 milligrams of gramicidin per milliliter in 10 percent acacia solution. Observe mice for 4 days.

(3) *Moisture.* Proceed as directed in § 141a.5(a) of this chapter.

(4) *Residue on ignition.* Proceed as directed in § 141e.401(g) of this chapter.

(5) *Melting point.* Proceed as directed in § 141d.301(h) of this chapter.

(6) *Identity.* Accurately weigh about 20 milligrams of the sample and dilute in ethyl alcohol to give a concentration of 0.02 milligram (estimated) of gramicidin per milliliter. Prepare a solution of the gramicidin working standard to contain 0.02 milligram per milliliter in ethyl alcohol. Using a suitable recording spectrophotometer with 1-centimeter cells, record the ultraviolet absorbance spectrum of each solution from 220 millimicrons to 320 millimicrons. The ultraviolet absorbance spectrum of the sample solution should compare qualitatively to that of the working standard solution. Determine the absorptivities of each at the maximum occurring at 282 millimicrons and at the minimum occurring at 247 millimicrons (the exact position of the maximum and minimum of the gramicidin working standard should be determined for the particular instrument used). The difference in the absorptivities of the sample is 100±4.0 percent of that of the working standard.

(7) *Crystallinity.* Proceed as directed in § 141a.5(c) of this chapter.

(Sec. 507, 59 Stat. 463, as amended, 76 Stat. 785, 786, 787; 21 U.S.C. 357)

PART 148h—KANAMYCIN SULFATE

Sec.

148h.1 Kanamycin sulfate.
148h.2 Kanamycin sulfate injection.
148h.3 Kanamycin sulfate capsules.

AUTHORITY: The provisions of this Part 148h issued under sec. 507, 59 Stat. 463, as amended 76 Stat. 785, 786, 787; 21 U.S.C.A. 357.

§ 148h.1 Kanamycin sulfate.

(a) *Requirements for certification*—(1) *Standards of identity, strength, quality, and purity.* Kanamycin sulfate is the crystalline sulfate salt of a kind of kanamycin or a mixture of two or more such salts. It is so purified and dried that:

(i) Its potency on the anhydrous basis is not less than 750 micrograms of kanamycin per milligram.

(ii) It is sterile.

(iii) It is nontoxic.

(iv) It is nonpyrogenic.

(v) Its moisture content is not more than 4 percent.

(vi) Its pH in an aqueous solution containing 10 milligrams per milliliter is not less than 6.5 and not more than 8.5.

(vii) Its residue on ignition is not more than 1.0 percent.

(viii) It gives a positive identity test for kanamycin.

(ix) It contains not more than 5.0 percent kanamycin B.

(2) *Labeling.* It shall be labeled in accordance with the requirements of § 148.3(b) of this chapter. Its expiration date is 12 months.

(3) *Request for certification.* In addition to the requirements of § 148.4 of this chapter, each such request shall contain:

(i) Results of tests and assays on the batch for potency, sterility, toxicity, pyrogens, moisture, pH, residue on ignition, identity, crystallinity, and kanamycin B content.

(ii) Samples required:

(*a*) For all tests except sterility: 10 packages, each containing approximately 500 milligrams.

(*b*) For sterility testing: 10 packages, each containing approximately 500 milligrams.

(4) *Fees.* $5.00 for each container submitted in accordance with subparagraph (3)(ii)(*a*) of this paragraph; $10.00 for all samples submitted in accordance with subparagraph (3)(ii)(*b*) of this paragraph.

(b) *Tests and methods of assay*—(1) *Potency*—(i) *Cylinders (cups).* Use cylinders described under § 141a.1(a) of this chapter.

(ii) *Culture medium.* Use ingredients that conform to the standards prescribed by the U.S.P. or N.F. Make nutrient agar as follows:

(*a*) For the base and seed layers:

Peptone	6.0 gm.
Pancreatic digest of casein	4.0 gm.
Yeast extract	3.0 gm.
Beef extract	1.5 gm.

Dextrose	1.0 gm.
Agar	15.0 gm.
Distilled water, q.s.	1,000 ml.

pH 7.8 to 8.0 after sterilization.

(b) Nutrient agar for carrying the test organism is the same as that described in (a) of this subdivision, except that the pH is 6.5 to 6.6 after sterilization.

In lieu of preparing the media from the individual ingredients specified in this subdivision, they may be made from a dehydrated mixture that, when reconstituted with distilled water, has the same composition as such media. Minor modification of the individual ingredients specified in this subdivision are permissible if the resulting media possess growth-promoting properties at least equal to the media described.

(iii) *Working standard.* Dissolve a suitable quantity of the working standard, accurately weighed, in sufficient 0.1*M* potassium phosphate buffer, pH 8.0, to give a convenient stock solution. The stock solution, when stored under refrigeration, may be used for a period not exceeding 1 month.

(iv) *Preparation of sample.* Dissolve a suitable quantity, accurately weighed, in 0.1*M* potassium phosphate buffer, pH 8.0, to give a convenient stock solution. Further dilute volumetrically in 0.1*M* potassium phosphate buffer, pH 8.0, to make a solution containing 5.0 micrograms of kanamycin per milliliter (estimated).

(v) *Preparation of test organism.* The test organism is *Staphylococcus aureus* (ATCC 6538P) which is maintained on agar described in subdivision (ii)(b) of this subparagraph. From a stock slant, inoculate a Roux bottle containing the same agar and incubate for 24 hours at 32° C. to 35° C. Wash the growth from the agar surface with 50 milliliters of sterile U.S.P. saline T.S. If an aliquot of this bulk suspension, when diluted 1:20 with sterile U.S.P. saline T.S., gives 25 percent light transmission in a suitable photoelectric colorimeter equipped with a filter having a wavelength of 580 mμ and a test tube with an inside diameter of 13 millimeters as an absorption cell, it is satisfactory for use. It may be necessary to adjust the bulk suspension by dilution, so that an aliquot of the adjusted suspension diluted 1:20 gives 25 percent light transmission. (The adjusted bulk suspension only, and not the 1:20 dilution of it, is used in preparing the seed layer.) The bulk suspension may be stored for 1 week under refrigeration. An aliquot of the adjusted bulk suspension is added to the agar described in subdivision (ii)(a) of this subparagraph, which has been melted and cooled to 48° C. Employ test plates to determine the quantity of the adjusted bulk suspension (usually 0.4 milliliter) to be added to each 100 milliliters of agar to give clear, sharp zones of inhibition of an appropriate size.

(vi) *Preparation of plates.* Add 21 milliliters of the agar prepared as described in subdivision (ii)(a) of this subparagraph to each Petri dish (20 millimeters x 100 millimeters). Distribute the agar evenly in the plates and allow to harden. Use the plates the same day they are prepared. Add 4.0 milliliters of the inoculum prepared as described in subdivision (v) of this subparagraph to each plate, tilting the plates back and forth to spread the inoculated agar evenly over the surface.

(vii) *Standard curve.* Prepare daily in 0.1*M* potassium phosphate buffer, pH 8.0, from the stock solution described in subdivision (iii) of this subparagraph, concentrations of 3.2, 4.0, 5.0, 6.25, and 7.81 micrograms per milliliter of solution. A total of 12 plates is used in the preparation of the standard curve, three plates for each solution except the 5.0 micrograms per milliliter solution. The latter concentration is used as the reference point and is included on each plate. On each of three plates, fill three cylinders with the 5.0 microgram per milliliter standard and the other three cylinders with the concentration under test. Thus, there will be thirty-six 5-microgram determinations and nine determinations for each of the other points on the curve. After the plates have incubated, read the diameters of the circles of inhibition. Average the readings of the 5.0 micrograms per milliliter concentration and the readings of the concentration tested for each set of three plates and average also all 36 readings of the 5.0 micrograms per milliliter concentration. The average of the 36 readings of the 5.0 micrograms per milliliter concentration is the correction point for the curve. Correct the average value obtained for each point to the figure it would be if the 5.0 micrograms per milliliter reading for that set of three plates were the same as the correction point. Thus, if in correcting the 4.0-microgram concentration, the average of the 36 readings of the 5.0 micrograms per milliliter concentration is 16.5 millimeters and the average of the 5.0 micrograms per milliliter concentration of this set of three plates is 16.3 millimeters, the correction is +0.2 millimeter. If the average readings of the 4.0 micrograms per milliliter concentration of these same three plates is 15.9 millimeters, the corrected value is then 16.1 millimeters. Plot these corrected values, including the average of the 5.0 micrograms per milliliter concentration, on 2-cycle semilog paper, using the concentration in micrograms per milliliter as the ordinate (the logarithmic scale) and the diameter of the zone of inhibition as the abscissa. Draw the standard curve through these points, either by inspection or by means of the following equations:

$$L=\frac{3a+2b+c-e}{5},$$

$$H=\frac{3e+2d+c-a}{5},$$

where:

L = Calculated zone diameter for the lowest concentration of the standard curve;

H = Calculated zone diameter for the highest concentration of the standard curve;

c = Average zone diameter of 36 readings of the 5.0 micrograms per milliliter standard;

a, b, d, e = Corrected average values for the 3.2, 4.0, 6.25, and 7.81 micrograms per milliliter solutions, respectively.

Plot the values obtained for L and H and connect wtih a straight line.

(viii) *Assay.* Place six cylinders on the inoculated agar surface in each Petri dish prepared as described in subdivision (vi) of this subparagraph, so that they are at approximately 60° intervals on 2.8-centimeter radius. Use three plates for each sample. Fill three cylinders on each plate with the 5.0 micrograms per milliliter standard and three cylinders with the 5.0 micrograms per milliliter (estimated) sample, alternating standard and sample. Incubate plates for 16 hours to 18 hours at 32° C. to 35° C., and measure the diameter of each circle of inhibition.

(ix) *Estimation of potency.* Average the zone readings of the standard and average the zone readings of the sample on the three plates used. If the sample gives larger average zone size than the average of the standard, add the difference between them to the 5.0-microgram zone sizes of the standard curve. If the average value is lower than the standard value, subtract the difference between them from the 5.0-microgram value on the curve. From the curve, read the potencies corresponding to these corrected values of zone sizes.

(2) *Sterility.* Using 500 milligrams from each container tested, proceed as directed in § 141a.2 of this chapter, except that neither penicillinase nor the control tube is used in the test for bacteria.

(3) *Toxicity.* Proceed as directed in § 141a.4 of this chapter, using 0.5 milliliter of a solution prepared by diluting the sample to approximately 2.0 milligrams of kanamycin per milliliter with sterile U.S.P. saline T.S.

(4) *Pyrogens.* Proceed as directed in § 141a.3 of this chapter, using a test dose of 1.0 milliliter per kilogram of solution containing 10 milligrams of kanamycin per milliliter of sterile, pyrogen-free U.S.P. saline T.S.

(5) *Moisture.* Proceed as directed in § 141a.5(a) of this chapter.

(6) *pH.* Proceed as directed in § 141a.5(b) of this chapter, using a solution containing 10 milligrams per milliliter.

(7) *Residue on ignition.* Proceed as directed in § 141e.401(g) of this chapter.

(8) *Identity.* Dissolve about 10 milligrams of kanamycin sulfate in 1 milliliter of water, and add 1 milliliter of a 1:500 solution of triketohydrindene hydrate in normal butyl alcohol, then add 0.5 milliliter of pyridine. Heat on a steam bath for 5 minutes, and add 10 milliliters of water; a deep-purple color is produced.

(9) *Kanamycin B content*—(i) *Cylinders (cups).* Use cylinders described under § 141a.1(a) of this chapter.

(ii) *Culture medium.* Use ingredients that conform to the standards prescribed by the U.S.P. or N.F. Make agar for the base and seed layers as follows:

Peptone	6.0 gm.
Yeast extract	3.0 gm.
Beef extract	1.5 gm.
Agar	15.0 gm.

ph 7.8 to 8.0 after sterilization.

(iii) *Working standard.* Dissolve a suitable quantity of the kanamycin sulfate reference standard, accurately weighed, in 0.1*M* potassium phosphate buffer, pH 8.0, to give a concentration equivalent to 1.0 milligram of kanamycin per milliliter.

(iv) *Preparation of sample.* To 50 milligrams, accurately weighed, of kanamycin sulfate in a suitable container (such as a 7.5-milliliter serum vial) add 2.5 milliliters of 6*N* hydrochloric acid, and tightly close the container. Heat in a water bath at 100° C. for 1 hour, and cool. Add 2 milliliters of 6*N* sodium hydroxide, then dilute with sterile 0.1*M* potassium phosphate buffer, pH 8.0, to obtain a concentration of the equivalent of 1 microgram of kanamycin B per milliliter (estimated).

(v) *Preparation of test organism.* Use Bacillus subtilis (ATCC 6633) maintained on the nutrient agar described in subdivision (ii)(*b*) of this subparagraph. From a stock slant, inoculate a Roux bottle containing approximately 300 milliliters of the same agar and incubate for 24 hours at 32° C. to 35° C. Prepare a spore suspension by the following method: Grow the organism for 5 days in a Roux bottle containing 300 milliliters of nutrient agar described in (ii) (*b*) of this subparagraph, modified by the addition of 300 milligrams of $MnSO_4 \cdot H_2O$ per liter of nutrient agar. Wash and heat-shock the spore suspension as described in (v)(*a*) of this subparagraph. Maintain the spore suspension under refrigeration. Determine by appropriate tests the quantity of spore suspension to be added to each 100 milliliters of agar for the secondary layer that will give clear, sharp zones of inhibition.

(vi) *Preparation of plates.* Add 21 milliliters of the agar prepared as described in this subparagraph to each Petri dish (20 millimeters x 100 millimeters). Distribute the agar evenly in the plates and allow to harden. Use the plates the same day they are prepared. Add 4.0 milliliters of the fresh daily inoculum described in subdivision (iv) of this subparagraph to each plate, tilting the plates back and forth to spread the inoculated agar evenly over the surface.

(vii) *Standard curve.* Prepare on the day of testing in 0.1*M* potassium phosphate buffer, pH 7.8 to 8.0, from the standard stock solution, sufficient volumes of the following concentrations: 0.64, 0.8, 1.0, 1.25, and 1.56 micrograms per milliliter. The 1.0 microgram per milliliter solution is the reference point of the standard curve. On each of three plates fill three cylinders with the 1.0 microgram per milliliter standard and the other three cylinders with the concentration under test. Thus, there will be thirty-six 1.0-microgram determinations and nine determinations for each of the other points on the curve. After the plates have incubated, read the diameters of the circles of inhibition. Average the readings of the 1.0 microgram per milliliter concentration and the readings of the concentration test for each set of three plates and average also all 36 readings of the 1.0 microgram per milliliter concentration. The average of the 36 readings of the 1.0 microgram per milliliter concentration is the correction point for the curve. Correct the average value obtained for each point to the figure it would be if the 1.0 microgram per milliliter reading for that set of three plates were the same as the correction point. Thus, if in correcting the 0.8-microgram concentration, the average of the 36 readings of the 1.0 microgram per milliliter concentration is 16.5 millimeters and the average of the 1.0 microgram per milliliter concentration of this set of three plates is 16.3 millimeters, the correction is +0.2 millimeter. If the average readings of the 0.8 microgram per milliliter concentration of these same three plates is 15.9 millimeters, the corrected value is 16.1 millimeters. Plot these corrected values, including the average of the 1.0 microgram per milliliter concentration, on 2-cycle semilogarithmic paper, using the concentration in micrograms per milliliter as the ordinate and the diameter of the zone of inhibition as the abscissa. Draw the standard curve through these points, either by inspection or by means of the following equations:

$$L=\frac{3a+2b+c-e}{5},$$

$$H=\frac{3e+2d+c-a}{5},$$

where:

L = Calculated zone diameter for the lowest concentration of the standard curve;

H = Calculated zone diameter for the highest concentration of the standard curve;

c = Average zone diameter of 36 readings of the 1.0 microgram per milliliter standard;

a, b, d, e = Corrected average values for the 0.64, 0.8, 1.0, 1.25, and 1.56 micrograms per milliliter solutions, respectively.

Plot the values obtained for L and H and connect with a straight line.

(viii) *Assay.* Place six cylinders on the inoculated agar surface in each Petri dish prepared as described in subdivision (vi) of this subparagraph, so that they are at approximately 60° intervals on a 2.8-centimeter radius. Use three plates for each sample. Fill three cylinders on each plate with the 1.0 microgram per milliliter standard and three cylinders with the 1.0 microgram (estimated) per milliliter sample, alternating standard and sample. Incubate plates for 16 hours to 18 hours at 32° C. to 35° C., and measure the diameter of each circle of inhibition.

(ix) *Estimation of kanamycin B content.* Average the zone readings of the standard and average the zone readings of the sample on the three plates used. If the sample gives larger average zone size than the average of the standard, add the difference between them to the 1.0-microgram zone sizes of the standard curve. If the average value is lower than the standard value, subtract the difference between them from the 1.0-microgram value on the curve. From the curve, read the kanamycin potencies corresponding to these corrected values of zone sizes. Multiply the observed potency by 100 and divide by 126, to obtain a value representing the potency in terms of the milligram equivalent of kanamycin B. The calculated amount of kanamycin B is not more than 5 percent of the content of kanamycin found in subparagraph (1)(i) of this paragraph.

(10) *Crystallinity.* Proceed as directed in § 141a.5(c) of this chapter.

§ 148h.2 Kanamycin sulfate injection.

(a) *Requirements for certification*—(1) *Standards of identity, strength, quality, and purity.* Kanamycin sulfate injection is an aqueous solution of kanamycin sulfate with suitable and harmless buffer substances and preservatives. It contains either 250 milligrams of kanamycin per milliliter or 1.0 gram of kanamycin per 3.0 milliliters. It is sterile. It is nontoxic. It is nonpyrogenic. Its pH is not less than 3.5 and not more than 5.0. The kanamycin sulfate used conforms to the standards prescribed by § 148h.1(a)(1) (i), (vii), (viii), and (ix). Each other substance used, if its name is recognized in the U.S.P. or N.F., conforms to the standards prescribed therefor by such official compendium.

(2) *Labeling.* (i) In addition to the requirements prescribed by § 148.3 of this chapter, the labeling of each package shall bear a warning to the effect that older patients and patients receiving a total dose of more than 20 grams of the drug should be carefully observed for signs of eighth-nerve damage. In patients with impaired kidney function or with prerenal azotemia, the risk of severe ototoxic reaction that may result in permanent deafness is sharply increased.

(ii) The expiration date is 12 months.

(3) *Request for certification.* In addition to the requirements of § 148.4 of this chapter, each such request shall contain:

(i) Results of tests and assays on:

(*a*) The kanamycin sulfate used in making the batch for potency, residue on ignition, moisture, identity, crystallinity, and kanamycin B content.

(*b*) The batch for potency, sterility, toxicity, pyrogens, histamine, and pH.

(ii) Samples required:

(*a*) The kanamycin sulfate used in making the batch: 10 packages, each containing approximately 500 milligrams.

(*b*) The batch:

(*1*) For all tests except sterility: Minimum of 10 immediate containers.

(*2*) For sterility testing: 10 immediate containers.

(*c*) In case of an initial request for certification, each other ingredient used in making the batch: One package of each containing approximately 5 grams.

(4) *Fees.* $4.00 for each container in the samples submitted in accordance with subparagraph (3)(ii) (*a*) and (*c*) of this paragraph; $5.00 for each container in the sample submitted in accordance with subparagraph (3)(ii)(*b*)(*1*) of this paragraph; $10.00 for all containers submitted in accordance with subparagraph (3)(ii)(*b*)(*2*) of this paragraph.

(b) *Tests and methods of assay*—(1) *Potency.* Proceed as directed in § 148h.1(b)(1), except prepare the sample for assay by introducing a representative aliquot of the solution equivalent to one dose into a 100-milliliter volumetric flask and dilute to mark with 0.1*M* potassium phosphate buffer, pH 8.0. Mix thoroughly and make to proper estimated dilutions in pH 8.0 buffer to the prescribed reference point. The average potency is satisfactory if the immediate containers contain not less than 90 percent and not more than 115 percent of the number of milligrams they are represented to contain.

(2) *Sterility.* Using the entire contents of single-dose containers or the equivalent of approximately 500 milligrams from each multiple-dose container tested, proceed as directed in § 141a.2 of this chapter, except that neither penicillinase nor the control tube is used in the test for bacteria.

(3) *Toxicity.* Proceed as directed in § 148h.1(b)(3).

(4) *Pyrogens.* Proceed as directed in § 148h.1(b)(4).

(5) *pH.* Proceed as directed in § 141a.5(b) of this chapter, using undiluted solution.

§ 148h.3 Kanamycin sulfate capsules.

(a) *Requirements for certification*—(1) *Standards of identity, strength, quality, and purity.* Kanamycin sulfate capsules are composed of crystalline kanamycin sulfate, with or without one or more suitable and harmless buffer substances, vegetable oils, preservatives, diluents, binders, lubricants, colorings, and flavorings, enclosed in gelatin capsules. Each capsule contains 500 milligrams of kanamycin. The moisture content is not more than 4.0 percent. The crystalline kanamycin sulfate used conforms to the standards prescribed by § 148h.1(a)(1) (i), (iii), (v), (vi), (vii), (viii), and (ix). Each other substance used, if its name is recognized in the U.S.P. or N.F., conforms to the standards prescribed therefor by such official compendium.

(2) *Labeling.* It shall be labeled in accordance with the requirements of § 148.3 of this chapter. Its expiration date is 12 months.

(3) *Request for certification.* In addition to the requirements of § 148.4 of this chapter, each such request shall contain:

(i) Results of tests and assays on:

(*a*) The kanamycin sulfate used in making the batch for potency, toxicity, moisture, pH, residue on ignition, identity, and kanamycin B content.

(*b*) The batch for potency and moisture.

(ii) Samples required:

(*a*) Kanamycin sulfate used in making the batch: 10 packages, each containing approximately 500 milligrams.

(*b*) The batch: Minimum of 30 capsules.

(*c*) In case of an initial request for certification, each other ingredient used in making the batch: One package of each containing approximately 5 grams.

(4) *Fees.* $0.75 for each capsule in the sample submitted in accordance with subparagraph (3)(ii)(*b*) of this paragraph; $4.00 for each immediate container submitted in accordance with subparagraph (3)(ii) (*a*) and (*c*) of this paragraph.

(b) *Tests and methods of assay*—(1) *Potency.* Proceed as directed in § 148h.1(b)(1), except prepare the sample for assay as follows: Place a representative number of capsules in a glass blending jar containing 500 milliliters of 0.1*M* potassium phosphate buffer, pH 7.8 to 8.0. Using a high-speed blender, blend 3 minutes to 5 minutes, and then remove an aliquot and make to the proper estimated dilution in pH 8.0 buffer.

The average potency of the capsules is satisfactory if they contain not less than 90 percent and not more than 115 percent of the number of milligrams they are represented to contain.

(2) *Moisture.* Proceed as directed in § 141a.5(a) of this chapter.

PART 148m—OLEANDOMYCIN

§ 148m.1 Oleandomycin phosphate.

(a) *Requirements for certification*—(1) *Standards of identity, strength, quality, and purity.* Oleandomycin phosphate is the crystalline phosphate salt of a kind of oleandomycin or a mixture of two or more such salts. It is so purified and dried that:

(i) Its potency is not less than 775 micrograms of oleandomycin per milligram.

(ii) It is sterile.

(iii) It is nonpyrogenic.

(iv) It is nontoxic.

(v) Its moisture content is not more than 5 percent.

(vi) Its pH in a solution containing 100 milligrams per milliliter is not less than 3.0 and not more than 6.0.

(vii) Its residue on ignition is not more than 1 percent.

(viii) Its heavy metals content is not more than 100 parts per million.

(ix) It gives a positive identity test.

(2) *Packaging.* In addition to the requirements of § 148.2 of this chapter, if it is packaged for dispensing and is intended for intravenous or intramuscular use it shall contain 500 milligrams of oleandomycin.

(3) *Labeling.* It shall be labeled in accordance with the requirements of § 148.3(b) of this chapter. Its expiration date is 12 months.

(4) *Request for certification.* In addition to the requirements of § 148.4 of this chapter, each such request shall contain:

(i) Results of tests and assays of the batch for potency, sterility, pyrogens, toxicity, moisture, pH, crystallinity, residue on ignition, heavy metals, and identity.

(ii) Samples of the batch:

(*a*) If the batch is packaged for repacking or for use as an ingredient in the manufacture of another drug:

(*1*) For all tests except sterility: 10 packages, each containing equal portions of not less than 500 milligrams.

(*2*) For sterility testing: 10 packages, each containing approximately 500 milligrams.

(*b*) If the batch is packaged for dispensing:

(*1*) For all tests except sterility: A minimum of 10 immediate containers of the batch.

(*2*) For sterility: 10 immediate containers of the batch.

(5) *Fees.* $5.00 for each container submitted in accordance with subparagraph (4)(ii) (*a*)(*1*) and (*b*)(*1*) of this paragraph; $10.00 for all samples submitted in accordance with subparagraph (4)(ii) (*a*)(*2*) and (*b*)(*2*) of this paragraph.

(b) *Tests and methods of assay*—(1) *Potency*—(i) *Cylinders (cups).* Use cylinders described in § 141a.1(a) of this chapter.

(ii) *Culture media*—(*a*) Make nutrient agar for the seed and base layers as follows:

Peptone	6.0 gm.
Pancreatic digest of casein	4.0 gm.
Yeast extract	3.0 gm.
Beef extract	1.5 gm.
Dextrose	1.0 gm.
Agar	15.0 gm.
Distilled water, q.s.	1,000.0 ml.

pH 7.8 to 8.0 after sterilization.

(*b*) Use the nutrient agar described in subsection (*a*) of this subdivision for maintaining the test organism, except that its pH after sterilization is 6.5 to 6.6. In lieu of preparing media from the individual ingredients specified in this subdivision, they may be made from a dehydrated mixture which, when reconstituted with distilled water, has the same composition as such media. Minor modifications of the individual ingredients specified in this subdivision are permissible if the resulting media possess growth-promoting properties at least equal to the media described.

(iii) *Working standard.* Dissolve a suitable weighed quantity (usually 25 milligrams or less) of the working standard in 2 milliliters of ethyl alcohol, then add sufficient 0.1*M* potassium phosphate buffer, pH 8.0, to give a concentration of 1,000 micrograms of oleandomycin base per milliliter. This stock solution may be kept in the refrigerator for 30 days.

(iv) *Preparation of sample.* Dissolve the sample in sufficient 0.1*M* potassium phosphate buffer, pH 8.0, to give a convenient stock solution. Further dilute in 0.1*M* potassium phosphate buffer, pH 8.0, to give a final concentration of 5.0 micrograms of oleandomycin per milliliter (estimated).

(v) *Preparation of test organism.* The test organism is Staphylococcus epidermidis (ATCC 12228), which is maintained on slants of agar described in subdivision (ii)(*b*) of this subparagraph. Wash the organism from the agar slant with 3 milliliters of sterile U.S.P. saline T.S. onto a large agar surface such as that provided by a Roux bottle containing 300 milliliters of the agar described in subdivision (ii)(*b*) of this subparagraph. Spread the suspension of organisms over the entire agar surface with the aid of sterile glass beads. Incubate for 24 hours at 32° C. to 35° C. and then wash the resulting growth from the agar surface with about 50 milliliters of sterile U.S.P. saline T.S. Standardize the suspension so that a 1:25 dilution of it will give 25 percent light transmission, using a suitable photoelectric colorimeter with a 580-millimicron filter and a 13-millimeter diameter test tube as an absorption cell. Run test plates to determine the quantity of the bulk suspension (usually 0.16 milliliter) that should be added to each 100 milliliters of agar to give clear, sharp zones of inhibition of appropriate size.

(vi) *Preparation of plates.* Add 21 milliliters of the agar prepared as described in subdivision (ii) (*a*) of this subparagraph to each Petri dish (20 millimeters x 100 millimeters). Distribute the agar evenly in the plates and allow it to harden. Use the plates the same day they are prepared. Melt a sufficient amount of the agar described in subdivision (ii) (*a*) of this subparagraph, cool to 48° C., add the proper amount of the test organism as described in subdivision (v) of this subparagraph, and mix thoroughly. Add 4 milliliters of this inoculated agar to each Petri dish. Distribute the agar evenly in the plates, cover with porcelain covers glazed on the outside, and allow to harden. After the agar has hardened, place 6 cylinders on the agar surface so that they are at approximately 60° intervals on a 2.8-centimeter radius.

(vii) *Standard curve* . Prepare the daily standard curve by further diluting the 1,000 micrograms per milliliter stock solution in 0.1*M* potassium phosphate buffer, pH 8.0, to obtain concentrations of 3.2, 4.0, 5.0, 6.25 and 7.80 micrograms of oleandomycin per milliliter. Use three plates for the determination of each point on the curve, except the 5.0 micrograms per milliliter concentration, a total of 12 plates. On each of three plates, fill three cylinders with the 5.0 micrograms per milliliter standard and the other three cylinders with the concentration under test. Thus, there will be thirty-six 5-microgram determinations and nine determinations for each of the other points on the curve. After incubation, read the diameters of the circles of inhibition in the plates. Average the readings of the 5.0 micrograms per milliliter concentration and the readings of the point tested for each set of three plates and average also all 36 readings of the 5.0 micrograms per milliliter concentration. The average of the 36 readings of the 5.0 micrograms per milliliter concentration is the correction point for the curve. Correct the average value obtained for each point to the figure it would be if the 5.0 micrograms per milliliter reading for that set of three plates were the same as the correction point. Thus, if in correcting the 4.0-microgram concentration, the average of the 36 readings of the 5.0 microgram concentration were 20 millimeters and the average of the 5.0-microgram concentration of this set of three plates were 19.8 millimeters, the correction would be +0.2 millimeter. If the average reading of the 4.0-microgram concentration of these same three plates were 19.0 millimeters, the corrected value would be 19.2 millimeters. Plot these corrected values, including the average of the 5.0 micrograms per milliliter concentration, on 2-cycle semilog paper, using the concentrations in micrograms per milliliter as the ordinate (the logarithmic scale) and the diameter of the zone of inhibition as the abscissa. Draw the standard curve through these points, either by inspection or by means of the following equations:

$$L=\frac{3a+2b+c-e}{5},$$

$$H=\frac{3e+2d+c-a}{5},$$

where:

L=Calculated zone diameter for the lowest concentration of the standard curve;
H=Calculated zone diameter for the highest concentration of the standard curve;
c=Average zone diameter of 36 readings of the 5.0 micrograms per milliliter standard;
a, b, d, e=Corrected average values for 3.2 4.0, 6.25, and 7.81 micrograms per milliliter standard solutions, respectively.

Plot the values obtained for L and H and connect with a straight line.

(viii) *Assay.* Use three plates for each sample. Fill three cylinders on each plate with the standard 5.0 micrograms per milliliter solution and three cylinders with the 5.0 micrograms per milliliter (estimated) sample, alternating standard and sample. Incubate all plates, including those containing the standard curve at 32° C.–35° C. overnight, and measure the diameter of each circle of inhibition. To estimate the potency of the sample, average the zone readings of the standard and the zone readings of the sample on the three plates used. If the sample gives a larger zone size than the average of the standard, add the difference between them to the 5.0 micrograms per milliliter zone on the standard curve. If the average sample value is lower than the standard value, subtract the difference between them from the 5.0 micrograms per milliliter value on the curve, and read the potencies corresponding to these corrected values of zone sizes.

(2) *Sterility.* Using 500 milligrams from each container tested, proceed as directed in § 141a.2 of this chapter, except that neither penicillinase nor the control tube is used in the test for bacteria.

(3) *Pyrogens.* Proceed as directed in § 141a.3 of this chapter, using sterile, pyrogen-free saline T.S. as a diluent, and inject 1.0 milliliter per kilogram of a solution containing 10 milligrams of oleandomycin per milliliter.

(4) *Toxicity.* Proceed as directed in § 141a.4 of this chapter, except inject 0.5 milliliter of a solution in sterile saline T.S. containing 8 milligrams of oleandomycin per milliliter.

(5) *Moisture.* Proceed as directed in § 141a.26(e) of this chapter, except use a sample of approximately 1 gram, accurately weighed.

(6) *pH.* Proceed as directed in § 141a.5(b) of this chapter, using a solution containing 100 milligrams of the sample per milliliter.

(7) *Crystallinity.* Proceed as directed in § 141a.5(c) of this chapter.

(8) *Residue on ignition.* Proceed as directed in § 141e.401(g) of this chapter.

(9) *Heavy metals*—(i) *Preparation of reagents*—(*a*) *Ammonia, T.S.* Prepare an aqueous solution containing not less than 9 grams and not more than 10 grams of NH_3 per 100 milliliters.

(*b*) *Diluted acetic acid.* Dilute 60.0 milliliters of glacial acetic acid with sufficient water to give a solution of 1,000 milliliters.

(*c*) *Hydrogen sulfide, T.S.* Prepare a saturated solution of hydrogen sulfide by passing H_2S into cold water for a sufficient time. It is suitable if it produces at once a copious precipitate when added to an equal volume of 1*N* ferric chloride. Prepare a fresh solution of hydrogen sulfide T.S. each time a metals test is performed.

(*d*) *Lead nitrate stock solution.* Dissolve 159.8 milligrams of lead nitrate with 100 milliliters of water to which has been added 1 milliliter of nitric acid, and adjust with water to a volume of 1,000 milliliters. Prepare and store this solution in glass containers free from soluble lead salts.

(*e*) *Standard lead solution.* Dilute a 10.0-milliliter aliquot of the lead nitrate stock solution to 100 milliliters with water. This solution must be freshly prepared each time a heavy metals test is performed. One milliliter of this standard lead solution represents a level of 10 parts per million of lead.

(ii) *Preparation of the sample.* Use the sulfated ash obtained in the ash content test, or if necessary ash a separate weighing of 1.0 gram, accurately weighed, or 0.5 gram if the heavy metals limit is more than 30 parts per million. If a separate weighing of the substance is made, carefully ignite in a porcelain crucible at a low temperature until thoroughly charred. The crucible may be loosely covered with a porcelain lid during the charring. Add to the contents of the crucible 2 milliliters of nitric acid and 5 drops of sulfuric acid, and cautiously heat until white fumes are evolved, then ignite, preferably in a muffle furnace at 500° C. to 600° C. for 3 hours or until the carbon is all burned off. After cooling, add 2 milliliters of hydrochloric acid, and slowly evaporate to dryness on a steam bath. Moisten the residue with 1 drop of hydrochloric acid, add 10 milliliters of hot water, and digest for 2 minutes. Add, dropwise, ammonia T.S. until the solution is just alkaline to litmus paper, then add, dropwise, diluted acetic acid until the solution is slightly acid to litmus paper, and then add an excess of 2 milliliters of the diluted acetic acid. Filter if necessary, wash the crucible and the filter with about 10 milliliters of water, and dilute to exactly 25 milliliters.

(iii) *Procedure.* Place in a 50-milliliter Nessler tube 2 milliliters of diluted acetic acid and exactly the quantity of standard lead solution containing the lead equivalent of the heavy metals limit specified for the substance to be tested and add water to make 25 milliliters. Transfer the 25-milliliter solution of the sample, subdivision (ii) of this subparagraph, to a 50-milliliter Nessler tube, and add 10 milliliters of hydrogen sulfide T.S. to each tube, mix, allow to stand for 10 minutes, and view downward over a white surface; the color of the solution of the sample should be no darker than the standard that contains the lead equivalent of the heavy metals limit of the test.

(10) *Identity.* Dissolve about 10 milligrams of oleandomycin phosphate in 5 milliliters of hydrochloric acid and heat the solution in a water bath; a greenish-yellow color is produced.

(Sec. 507, 59 Stat. 463, as amended, 76 Stat. 785, 786, 787; 21 U.S.C. 357)

Effective date. This order shall become effective 60 days from the date of its publication in the FEDERAL REGISTER.

(Sec. 507, 59 Stat. 463 as amended; 21 U.S.C. 357)

Dated: June 2, 1964.

GEO. P. LARRICK,
Commissioner of Food and Drugs.

[F.R. Doc. 64-5686; Filed, June 12, 1964; 8:45 a.m.]

TESTS AND METHODS OF ASSAY AND CERTIFICATION OF ANTIBIOTIC DRUGS SUBJECT TO DRUG AMENDMENTS OF 1962

The Commissioner of Food and Drugs has evaluated the views and comments received in response to the notice of proposed rulemaking published in the FEDERAL REGISTER of May 2, 1963 (28 F.R. 4382), and has concluded that the following regulations should issue for the certification of certain antibotic drugs subject to the Drug Amendments of 1962 (76 Stat. 785–787; Public Law 87–781). Therefore, pursuant to the provisions of the Federal Food, Drug, and Cosmetic Act (sec. 507, 59 Stat. 463 as amended; 21 U.S.C. 357), and under the authority delegated to him by the Secretary of Health, Education, and Welfare (21 CFR 2.90; 29 F.R. 471), Title 21 is amended as hereinafter set forth. Included in this order are three sections (148e.29, 148e.30, and 148e.31) not included in any prior notice. Section 148e.29 *Erythromycin ethylsuccinate chewable tablets* and § 148e.30 *Erythromycin estolate chewable tablets* are new dosage forms developed since publication of the notice of proposed rulemaking of May 2, 1963. These new erythromycin preparations have been found to be safe and efficacious, conditions prerequisite to their certification, and are therefore incorporated in the part assigned to other erythromycin preparations. The information on which § 148e.31 *Erythromycin ophthalmic ointment* is based was included in the notice of proposed rulemaking of May 2, 1963, under § 148e.14 *Erythromycin ointment.* As proposed, § 148e.14 included erythromycin topical ointment and erythromycin ophthalmic ointment. In this order the two types of ointment are assigned individual monographs.

PART 146—GENERAL REGULATIONS FOR THE CERTIFICATION OF ANTIBIOTIC AND ANTIBIOTIC-CONTAINING DRUGS

1. Section 146.1 is amended in the following respects:

a. By adding to paragraph (c) (1) the following new subdivisions:

§ 146.1 Definitions and interpretations applicable to all certifiable antibiotic drugs.

* * * * *

(c) * * *

(1) * * *

(iii) The term "unit" applied to nystatin means the nystatin activity (potency) contained in 0.2817 microgram of the nystatin master standard when dried for 2 hours at 40° C. and a pressure of 5 millimeters or less.

(iv) The term "unit" applied to polymyxin B means the polymyxin activity (potency) contained in 1.2739 micrograms of the polymyxin B master standard when dried for 3 hours at 60° C. and a pressure of 5 millimeters or less.

b. By adding to paragraph (c) (2) the following new subdivisions:

(c) * * *

(2) * * *

(x) The term "microgram" applied to amphomycin means the amphomycin activity (potency) contained in 0.9355 microgram of the amphomycin master standard when dried for 4 hours at 60° C. and a pressure of 5 millimeters or less.

(xi) The term "microgram" applied to amphotericin A means the amphotericin A activity (potency) contained in 1.0 microgram of the amphotericin A master standard when dried for 3 hours at 60° C. and a pressure of 5 millimeters or less.

(xii) The term "microgram" applied to amphotericin B means the amphotericin B activity (potency) contained in 1.124 micrograms of the amphotericin B master standard when dried for 3 hours at 60° C. and a pressure of 5 millimeters or less.

(xiii) The term "microgram" applied to colistin means the colistin base activity (potency) contained in 1.495 micrograms of the colistin master standard when dried for 3 hours at 60° C. and a pressure of 5 millimeters or less.

(xiv) The terms "microgram" applied to colistimethate means the activity (potency) calculated as colistin base that is contained in 1.938 micrograms of the colistimethate master standard when dried for 3 hours at 60° C. and a pressure of 5 millimeters or less.

(xv) The term "microgram" applied to cycloserine means the cycloserine activity (potency) contained in 1.0 microgram of the cycloserine master standard when dried for 3 hours at 60° C. and a pressure of 5 millimeters or less.

(xvi) The term "microgram" applied to erythromycin means the erythromycin base activity (potency) contained in 1.02 micrograms of the erythromycin master standard when dried for 3 hours at 60° C. and a pressure of 5 millimeters or less.

(xvii) The term "microgram" applied to gramicidin means the gramicidin activity (potency) contained in 1.0 microgram of the gramicidin master standard when dried for 3 hours at 60° C. and a pressure of 5 millimeters or less.

(xviii) The term "microgram" applied to griseofulvin means the griseofulvin activity (potency) contained in 1.0 microgram of the griseofulvin master standard.

(xix) The term "microgram" applied to kanamycin means the kanamycin base activity (potency) contained in 1.299 micrograms of the kanamycin master standard.

(xx) The term "microgram" applied to neomycin means the neomycin base activity (potency) contained in 1.429 micrograms of the neomycin master standard when dried for 3 hours at 60° C. and a pressure of 5 millimeters or less.

(xxi) The term "microgram" applied to novobiocin means the novobiocin acid activity (potency) contained in 1.033 micrograms of the novobiocin master standard when dried for 3 hours at 60° C. and a pressure of 5 millimeters or less.

(xxii) The term "microgram" applied to oleandomycin means the oleandomycin base activity (potency) contained in 1.176 micrograms of the oleandomycin master standard.

(xxiii) [Reserved]

(xxiv) The term "microgram" applied to oxytetracycline means the oxytetracycline base activity (potency) contained in 1.13 micrograms of the oxytetracyline master standard.

(xxv) The term "microgram" applied to paromomycin means the paromomycin base activity (potency) contained in 1.333 micrograms of paromomycin master standard.

(xxvi) The term "microgram" applied to tyrothricin means the activity (potency) contained in 0.2 microgram of the gramicidin master standard when dried for 3 hours at 60° C. and a pressure of 5 millimeters or less.

(xxvii) The term "microgram" applied to vancomycin means the vancomycin base activity (potency) contained in 1.25 micrograms of the vancomycin master standard.

(xxviii) The term "microgram" applied to viomycin means the viomycin base activity (potency) contained in 1.355 micrograms of the viomycin master standard when dried for 3 hours at 60° C. and a pressure of 5 millimeters or less.

c. By adding to paragraph (d) the following new subparagraphs:

(d) * * *

(2) The term "amphotericin A working standard" means a specific lot of a homogeneous preparation of amphotericin A.

(3) The term "amphotericin B working standard" means a specific lot of a homogeneous preparation of amphotericin B.

* * * * *

(12) The term "amphomycin working standard" means a specific lot of a homogeneous preparation of amphyomycin.

(13) The term "colistin working standard" means a specific lot of a homogeneous preparation of colistin.

(14) The term "colistimethate working standard" means a specific lot of a homogeneous preparation of colistimethate.

(15) The term "cycloserine working standard" means a specific lot of a homogeneous preparation of cycloserine.

(16) The term "erythromycin working standard" means a specific lot of a homogeneous preparation of erythromycin.

(17) The term "gramicidin working standard" means a specific lot of a homogeneous preparation of gramicidin.

(18) The term "griseofulvin working standard" means a specific lot of a homogeneous preparation of griseofulvin.

(19) The term "kanamycin working standard" means a specific lot of a homogeneous preparation of kanamycin.

(20) The term "neomycin working standard" means a specific lot of a homogeneous preparation of neomycin.

(21) The term "novobiocin working standard" means a specific lot of a homogeneous preparation of novobiocin.

(22) The term "nystatin working standard" means a specific lot of a homogeneous preparation of nystatin.

(23) The term "oleandomycin working standard" means a specific lot of a homogeneous preparation of oleandomycin.

(24) [Reserved]

(25) The term "oxytetracycline working standard" means a specific lot of a homogeneous preparation of oxytetracycline.

(26) The term "paromomycin working standard" means a specific lot of a homogeneous preparation of paromomycin.

(27) The term "polymyxin B working standard" means a specific lot of a homogeneous preparation of polymyxin B.

(28) The term "vancomycin working standard" means a specific lot of a homogeneous preparation of vancomycin.

(29) The term "viomycin working standard" means a specific lot of a homogeneous preparation of viomycin.

d. By changing paragraph (g) and the introduction to paragraph (h) to read:

(g) Except as specifically provided by the regulations in this chapter, no provision of any regulation shall be construed as exempting any certifiable antibiotic drug from any applicable provision of the act or any regulation thereunder.

(h) The regulations in this chapter, prescribing tests and methods of assay for antibiotic and antibiotic-containing drugs, shall not be construed as preventing the Commissioner from using any other test or method of assay in his investigations to determine whether or not:

2. Title 21, Chapter I, is amended by adding thereto the following new parts: [1]

PART 148e—ERYTHROMYCIN

Sec.
148e.1 Erythromycin.
148e.2 Erythromycin ethylcarbonate.
148e.3 Erythromycin gluceptate.
148e.4 [Reserved]
148e.5 Erythromycin estolate.
148e.6 Erythromycin stearate.
148e.7 Erythromycin ethylsuccinate.
148e.8 Erythromycin sulfate.
148e.9 Erythromycin ethylsuccinate-sulfanilamide dental powder.
148e.10 Erythromycin ethylsuccinate granules for oral suspension.
148e.11 Erythromycin ethylcarbonate for oral suspension.
148e.12 Erythromycin estolate for oral suspension.
148e.13 Erythromycin ethylsuccinate oral suspension.
148e.14 Erythromycin ointment.
148e.15 Erythromycin-neomycin sulfate ointment.
Sec.
148e.16 Erythromycin-polymyxin β sulfate ointment.
148e.17 Erythromycin estolate capsules.
148e.18 [Reserved]
148e.19 Erythromycin gluceptate dental cones.
148e.20 Erythromycin gluceptate-polymyxin β sulfate-benzocaine for otic solution.
148e.21 Erythromycin sulfate-polymyxin β sulfate-pramoxine hydrochloride otic solution.
148e.22 Erythromycin estolate for pediatric drops.
148e.23 [Reserved]
148e.24 Erythromycin enteric-coated tablets.
148e.25 Erythromycin lactobionate for intravenous infusion.
148e.26 Erythromycin tablets.
148e.27 Erythromycin stearate tablets.
148e.28 Erythromycin estolate tablets with sulfonamides.
148e.29 Erythromycin ethylsuccinate chewable tablets.
148e.30 Erythromycin estolate chewable tablets.
148e.31 Erythromycin ophthalmic ointment.

AUTHORITY: The provisions of this Part 148e issued under sec. 507, 59 Stat. 463, as amended 76 Stat. 785, 786, 787; 21 U.S.C. 357.

§ 148e.1 Erythromycin.

(a) *Requirements for certification*—(1) *Standards of identity, strength, quality, and purity.* Erythromycin is the odorless, white to grayish-white or slightly yellow crystalline compound of a kind of erythromycin or a mixture of two or more such compounds. It is so purified and dried that:

(i) It contains not less than 850 micrograms of erythromycin per milligram calculated on an anhydrous basis.

(ii) It is nontoxic.

(iii) Its moisture content is not more than 10 percent.

(iv) Its pH in a saturated aqueous solution, prepared by using 100 milligrams of erythromycin per milliliter, is not less than 8.0 nor more than 10.5.

(v) Its residue on ignition is not more than 2.0 percent.

(vi) Its heavy metals content is not more than 50 parts per million.

(vii) It gives a positive identity test for erythromycin.

(2) *Labeling.* It shall be labeled in accordance with the requirements of § 148.3 of this chapter. Its expiration date is 12 months.

(3) *Request for certification; samples.* In addition to the requirements of § 148.4 of this chapter, each such request shall contain:

(i) Results of tests and assays on the batch for potency, toxicity, moisture, residue on ignition, heavy metals, pH, identity, and crystallinity.

(ii) Samples required: 10 packages, each containing not less than 500 milligrams.

(4) *Fees.* $4.00 for each container submitted in accordance with subparagraph (3)(ii) of this paragraph.

(b) *Tests and methods of assay*—(1) *Potency* (i) *Cylinders (cups).* Use cylinders described under § 141a.1(a) of this chapter.

(ii) *Culture media.* Use ingredients that conform to the standards prescribed by the U.S.P. or N.F. Make nutrient agar as follows:

(*a*) For carrying the test organism:

Peptone	6.0 gm.
Pancreatic digest of casein	4.0 gm.
Yeast extract	3.0 gm.
Beef extract	1.5 gm.
Dextrose	1.0 gm.
Agar	15.0 gm.
Distilled water, q.s	1,000.0 ml.

pH 6.5 to 6.6 after sterilization.

(*b*) For base and seed layers: Same formulation as in (*a*), except adjust the medium to pH 8.0 after sterilization.

In lieu of preparing the media from the individual ingredients specified in this subdivision, they may be made from a dehydrated mixture which, when reconstituted with distilled water, has the same composition as such media. Minor modifications of the individual ingredients specified in this subdivision are permissible if the resulting media possess growth-promoting properties at least equal to the media described.

(iii) *Working standard.* Dry approximately 30 milligrams of the working standard for 3 hours at 60° C. and a pressure of 5 millimeters or less. Determine the dry weight and dissolve the dried working standard in sufficient methyl alcohol to give a concentration of 10,000 micrograms of erythromycin base per milliliter. Further dilute with 0.1*M* potassium phosphate buffer, pH 8.0, to give a stock solution of 1,000 micrograms of erythromycin base per milliliter. This stock solution may be kept under refrigeration for 14 days.

(iv) *Preparation of sample.* Dissolve an accurately weighed amount of the sample (approximately 50 milligrams) in approximately 5.0 milliliters of methyl alcohol and further dilute in 0.1*M* potassium phosphate buffer, pH 8.0, to make a solution containing 1.0 milligram of erythromycin base per milliliter (estimated). Further dilute an aliquot to the reference point of the assay with 0.1*M* potassium phosphate buffer, pH 8.0.

(v) *Preparation of test organism.* The test organism is *Sarcina lutea* (ATCC 9341), which is maintained on slants of agar described under (ii)(*a*) of this subparagraph. Wash the organism from the agar slant with 3 milliliters of sterilized U.S.P. saline T.S. onto a large agar surface such as that provided by a Roux bottle containing 300 milliliters of the agar described in (ii)(*a*) of this subparagraph. Spread the suspension of organism over the entire agar surface with the aid of sterile glass beads. Incubate for 24 hours at 32° C.–35° C., and then wash the resulting growth from the agar surface with about 50 milliliters of sterilized U.S.P. saline T.S. Standardize the suspension so that a 1:40 dilution of it will give 25 percent light transmission, using a suitable photoelectric colorimeter with a 580-millimicron filter and a 13-millimeter diameter test tube as an absorption cell. Run test plates to determine the quantity of the bulk suspension (usually 1.5 milliliters) that should be added to each 100 milliliters of agar to give clear, sharp zones of inhibition of appropriate size.

(vi) *Preparation of plates.* Add 21 milliliters of the agar prepared as described in (ii)(*b*) of this subparagraph to each Petri dish (20 millimeters x 100 millimeters). Distribute the agar evenly on the plates and allow it to harden. Use the plates the same day they are prepared. Melt a sufficient amount of the agar described in (ii) (*b*) of this subparagraph, cool to 48° C., add the proper amount of the test organism as described in (v) of this subparagraph, and mix thoroughly. Add 4 milliliters of this inoculated agar to each Petri dish. Distribute the agar evenly on the plates, cover with porcelain covers glazed on the outside, and allow to harden. After the agar has hardened, place six cylinders on the agar surface so that they are at approximately 60° intervals on a 2.8-centimeter radius.

---

[1] Certain portions of the proposal will be covered by a subsequent order.

(vii) *Standard curve.* Prepare daily in 0.1*M* potassium phosphate buffer, pH 8.0, from the stock solution described in (iii) of this subparagraph, concentrations of 0.64, 0.80, 1.0, 1.25, and 1.56 micrograms of erythromycin per milliliter. A total of 12 plates is used in the preparation of the standard curve, three plates for each solution except the 1.0 microgram per milliliter solution. The latter concentration is used as the reference point and is included on each plate. On each of three plates fill three cylinders with the 1.0 microgram per milliliter standard and the other three cylinders with the concentration under test. Thus, there will be thirty-six 1-microgram determinations and nine determinations for each of the other points on the curve. After the plates have incubated, read the diameters of the circles of inhibition. Average the readings of the 1.0 microgram per milliliter concentration and the readings of the point tested for each set of three plates, and average also all 36 readings of the 1.0 microgram per milliliter concentration. The average of the 36 readings of the 1.0 microgram per milliliter concentration is the correction point for the curve. Correct the average value obtained for each point to the figure it would be if the 1.0 microgram per milliliter reading for that set of three plates were the same as the correction point. Thus, if in correcting the 0.8-microgram concentration, the average of the 36 readings of the 1.0 microgram per milliliter concentration is 16.5 millimeters and the average of the 1.0 microgram per milliliter concentration of this set of three plates is 16.3 millimeters, the correction is 0.2 millimeter. If the average readings of the 0.8 microgram per millimeter concentration of these same three plates is 15.9 millimeters, the corrected value is then 16.1 millimeters. Plot these corrected values, including the average of the 1.0 microgram per milliliter concentration, on 2-cycle semilog paper, using the concentration in micrograms per milliliter as the ordinate (the logarithmic scale) and the diameter of the zone of inhibition as the abscissa. Draw the standard curve through these points, either by inspection or by means of the following equations:

$$L=\frac{3a+2b+c-e}{5},$$

$$H=\frac{3e+2d+c-a}{5},$$

where:

L=Calculated zone diameter for the lowest concentration of the standard curve;

H=Calculated zone diameter for the highest concentration of the standard curve;

c=Average zone diameter of 36 readings of the 1.0 micrograms per milliliter standard;

a, b, d, e=Corrected average values for 0.64, 0.80, 1.25, and 1.56 micrograms per milliliter solutions, respectively.

Plot the values obtained for L and H and connect with a straight line.

(viii) *Assay.* Use three plates for each sample. Fill three cylinders on each plate with the standard 1.0 microgram per milliliter solution and three cylinders with the 1.0 microgram per milliliter (estimated) sample, alternating standard and sample. Incubate all plates, including those containing the standard curve, at 32° C.–35° C. overnight, and measure the diameter of each circle of inhibition. To estimate the potency of the sample, average the zone readings of the standard and the zone readings of the sample on the three plates used. If the sample gives a larger zone size than the average of the standard, add the difference between them to the 1.0 microgram per milliliter zone on the standard curve. If the average sample value is lower than the standard value, subtract the difference between them from the 1.0 microgram per milliliter value on the curve. From the standard curve, read the potencies corresponding to the corrected values of zone sizes.

(2) *Toxicity.* Proceed as directed in § 141d.305(b) of this chapter, except administer orally 1.0 milliliter of a suspension of the drug containing 30 milligrams of erythromycin per milliliter in 10-percent acacia solution.

(3) *Moisture.* Proceed as directed in § 141a.26(e) of this chapter.

(4) *pH.* Using a saturated aqueous solution (100 milligrams of erythromycin per milliliter) proceed as directed in § 141a.5(b) of this chapter.

(5) *Residue on ignition.* Proceed as directed in § 141e.401(g) of this chapter.

(6) *Heavy metals.* Proceed as described in § 148m.1(b) (9) of this chapter.

(7) *Crystallinity.* Proceed as directed in § 141a.5(c) of this chapter.

(8) *Identity test.* The infrared absorption, in the spectrum from 2 microns to 12 microns, of a 5 percent solution of the sample in chloroform compares qualitatively to that of the erythromycin working standard similarly treated.

§ 148e.2 Erythromycin ethylcarbonate.

(a) *Requirements for certification*—(1) *Standards of identity, strength, quality, and purity.* Erythromycin ethylcarbonate is a white, crystalline ester of erythromycin obtained by the reaction of a kind of erythromycin and chloroethylcarbonate. It is slightly soluble in water, freely soluble in alcohol, methyl alcohol, acetone, ether, and chloroform. It is so purified and dried that:

(i) It contains not less than 775 micrograms of erythromycin base per milligram, calculated on an anhydrous basis.

(ii) It is nontoxic.

(iii) Its moisture content is not more than 8 percent.

(iv) Its pH is not less than 6.3 and not more than 8.0.

(v) It gives a positive identity test for erythromycin ethylcarbonate.

(2) *Labeling.* It shall be labeled in accordance with the requirements prescribed by § 148.3 of this chapter. Its expiration date is 12 months.

(3) *Request for certification; samples.* In addition to the requirements of § 148.4 of this chapter, each such request shall contain:

(i) Results of tests and assays on the batch for potency, toxicity, moisture, pH, identity, and crystallinity.

(ii) Samples required: 10 containers, each containing not less than 300 milligrams.

(4) *Fees.* $4.00 for each container in the sample submitted in accordance with subparagraph (3) (ii) of this paragraph.

(b) *Tests and methods of assay*—(1) *Potency.* Proceed as directed in § 148e.1 (b) (1), except to prepare the sample, wash an accurately weighed amount of the sample (approximately 50 milligrams) into a 100-milliliter volumetric flask, using approximately 40 milliliters of absolute methyl alcohol. Immediately dilute to volume with sterile distilled water. Place this solution in a 60° C. water bath for 3 hours or allow it to remain at room temperature for 40 hours to 48 hours to accomplish hydrolysis. Adjust the volume to 100 milliliters with sterilized distilled water and mix well. Further dilute an aliquot to the reference point of the assay with 0.1*M* potassium phosphate buffer, pH 8.0.

(2) *Toxicity.* Proceed as directed in § 141d.305(b) of this chapter, except administer 0.5 milliliter of a suspension containing 100 milligrams of erythromycin per milliliter in a 10 percent acacia solution.

(3) *Moisture.* Proceed as directed in § 141a.26(e) of this chapter.

(4) *pH.* Proceed as directed in § 141a.5(b) of this chapter, using a concentration of 200 milligrams per milliliter.

(5) *Identity tests.* Proceed as directed in § 148e.1(b) (8), except that an authentic erythromycin ethylcarbonate is used as the sample of comparison.

(6) *Crystallinity.* Proceed as directed in § 141a.5(c) of this chapter.

§ 148e.3 Erythromycin gluceptate.

(a) *Requirements for certification*—(1) *Standards of identity, strength, quality, and purity.* Erythromycin gluceptate is the white powder of the glucoheptonic acid salt of erythromycin or a mixture of two or more such salts. It is freely soluble in water, alcohol, and methyl alcohol. It is slightly soluble in acetone and chloroform, but is practically insoluble in ether. It is so purified and dried that:

(i) It contains not less than 600 micrograms of erythromycin per milligram, calculated on an anhydrous basis.

(ii) It is sterile.

(iii) It is nontoxic.

(iv) It is nonpyrogenic.

(v) Its moisture content is not more than 5.0 percent.

(vi) Its pH in an aqueous solution containing 25 milligrams per milliliter is not less than 6.0 nor more than 8.0.

(vii) It gives a positive identity test for erythromycin gluceptate.

(2) *Packaging.* In addition to the requirements of § 148.2 of this chapter if it is packaged for dispensing and intended for intravenous use, it shall contain the equivalent of 250 milligrams, 500 milligrams, or 1.0 gram of erythromycin per vial.

(3) *Labeling.* It shall be labeled in accordance with the requirements of § 148.3 of this chapter. Its expiration date is 12 months.

(4) *Request for certification; samples.* In addition to the requirements of § 148.4 of this chapter, each such request shall contain:

(i) Results of tests and assays on the batch for potency, sterility, toxicity, pyrogens, moisture, pH, and identity.

(ii) Samples required:

(*a*) If the batch is packaged for repacking or for use as an ingredient in the manufacture of another drug:

(*1*) For all tests except sterility: 10 packages, each containing not less than 300 milligrams.

(*2*) For sterility testing: 10 packages, each containing approximately 500 milligrams.

(*b*) If the batch is packaged for dispensing:

(*1*) For all tests except sterility: A minimum of 10 immediate containers of the batch.

(*2*) For sterility: 10 immediate containers of the batch.

(5) *Fees.* $5.00 for each container submitted in accordance with subparagraph (4)(ii) (*a*)(*1*) and (*b*)(*1*) of this paragraph; $10.00 for all samples submitted in accordance with subparagraph (4)(ii)(*a*)(2) and (*b*)(2) of this paragraph.

(b) *Tests and methods of assay*—(1) *Potency.* Proceed as directed in § 148e.1(b)(1), except when packaged for dispensing dissolve the sample as directed in the labeling and further dilute with 0.1*M* potassium phosphate buffer, pH 8.0. If it is packaged for dispensing, its potency is satisfactory if it is not less than 90 percent nor more than 115 percent of the number of milligrams of erythromycin that it is represented to contain.

(2) *Sterility.* Use 500 milligrams from each container tested, and proceed as directed in § 141a.2 of this chapter, except that neither the penicillinase nor the control tube is used in the test for bacteria.

(3) *Pyrogens.* Proceed as directed in § 141a.3 of this chapter, using a test dose of 1 milliliter per kilogram of a solution in pyrogen-free distilled water containing 30 milligrams of erythromycin per milliliter.

(4) *Toxicity.* Proceed as directed in § 141a.4 of this chapter, using a test dose of 0.5 milliliter of a solution in sterilized distilled water containing 2 milligrams of erythromycin base per milliliter.

(5) *Moisture.* Proceed as directed in § 141a.26(e) of this chapter.

(6) *pH.* Proceed as directed in § 141a.5(b) of this chapter, using a concentration of 25 milligrams per milliliter.

(7) *Identity.* The infrared absorption spectrum of a liquid petrolatum dispersion compares qualitatively to that of a similarly treated authentic sample of erythromycin gluceptate.

§ 148e.4 [Reserved]

§ 148e.5 Erythromycin estolate.

(a) *Requirements for certification*—(1) *Standards of identity, strength, quality, and purity.* Erythromycin estolate is the lauryl sulfate salt of the propionyl ester of a kind of erythromycin or a mixture of two or more such salts. It occurs as a white crystalline powder. It is soluble in alcohol, methyl alcohol, acetone, and chloroform, but is practically insoluble in water. It is so purified and dried that:

(i) It contains not less than 600 micrograms of erythromycin per milligram, calculated on an anhydrous basis.

(ii) It is nontoxic.

(iii) Its moisture content is not more than 4.0 percent.

(iv) Its pH is not less than 4.5 nor more than 7.0.

(v) It gives positive identity tests for erythromycin estolate.

(2) *Labeling.* It shall be labeled in accordance with the requirements of § 148.3 of this chapter. Its expiration date is 12 months.

(3) *Request for certification; samples.* In addition to the requirements of § 148.4 of this chapter, each such request shall contain:

(i) Results of tests and assays on the batch for potency, toxicity, moisture, pH, identity, and crystallinity.

(ii) Samples of the batch: A minimum of 10 containers, each containing not less than 300 milligrams.

(4) *Fees.* $4.00 for each container in the sample submitted in accordance with subparagraph (3)(ii) of this paragraph.

(b) *Tests and methods of assay*—(1) *Potency.* Proceed as directed in § 148e.1 (b)(*1*) of this chapter, except to prepare the sample transfer approximately 100 milligrams, accurately weighed, to a 100-milliliter volumetric flask. Dissolve in 40 milliliters of absolute methyl alcohol and immediately dilute to volume with 0.1*M* potassium phosphate buffer, pH 8.0. Hydrolyze this solution in a 60° C. constant temperature water bath for 2 hours or at room temperature for 16 to 18 hours.

(2) *Toxicity.* Proceed as directed in § 141d.305(b) of this chapter, except administer 0.5 milliliter of a suspension containing 40 milligrams of erythromycin per milliliter in a 10 percent acacia solution.

(3) *Moisture.* Proceed as directed in § 141a.26(e) of this chapter.

(4) *pH.* Proceed as directed in § 141a.5(b) of this chapter, using an aqueous suspension containing 100 milligrams per milliliter.

(5) *Crystallinity.* Proceed as directed in § 141a.5(c) of this chapter.

(6) *Identity test.* Proceed as directed in § 148e.1(b)(8), except compare the infrared absorption spectrum with that of an authentic sample of erythromycin estolate.

§ 148e.6 Erythromycin stearate.

(a) *Requirements for certification*—(1) *Standards of identity, strength, quality, and purity.* Erythromycin stearate is the odorless white or slightly yellow crystalline powder of the stearic acid salt of erythromycin. It is practically insoluble in water but is soluble in alcohol, methyl alcohol, chloroform, and ether. It is so purified and dried that:

(i) It contains not less than 500 micrograms of erythromycin per milligram, calculated on an anhydrous basis.

(ii) It is nontoxic.

(iii) Its moisture content is not more than 5.0 percent.

(iv) Its pH is not less than 6.0 and not more than 11.0.

(v) Its residue on ignition is not more than 2.0 percent.

(vi) It gives positive identity tests for erythromycin stearate.

(2) *Labeling.* It shall be labeled in accordance with the requirements of § 148.3 of this chapter. Its expiration date is 12 months.

(3) *Request for certification; samples.* In addition to the requirements of § 148.4 of this chapter, each such request shall contain:

(i) Results of tests and assays on the batch for potency, toxicity, moisture, pH, residue on ignition, identity, and crystallinity.

(ii) Samples required: A minimum of 10 containers, each consisting of 500 milligrams.

(4) *Fees.* $4.00 for each container in the sample submitted in accordance with subparagraph (3)(ii) of this paragraph.

(b) *Tests and methods of assay*—(1) *Potency.* Proceed as directed in § 148e.1 (b)(1), except prepare the sample in the following manner: Dissolve 50 milligrams, accurately weighed, in sufficient absolute methyl alcohol to give an estimated concentration of 1 milligram of erythromycin per milliliter.

(2) *Toxicity.* Proceed as directed in § 141d.305(b) of this chapter, except administer 0.5 milliliter of a suspension containing 80 milligrams of erythromycin per milliliter, prepared by grinding the sample in sterile distilled water, using 1 drop of polysorbate 80 per 3 grams of sample.

(3) *Moisture content.* Proceed as directed in § 141a.26(e) of this chapter.

(4) *pH.* Proceed as directed in § 141a.5(b) of this chapter, using a 1 percent slurry of erythromycin stearate in water.

(5) *Residue on ignition.* Proceed as directed in § 141e.401(g) of this chapter.

(6) *Identity.* Proceed as directed in § 148e.1(b)(8), except compare qualitatively the infrared absorption spectrum with that of an authentic sample of erythromycin stearate.

(7) *Crystallinity.* Proceed as directed in § 141a.5(c) of this chapter.

§ 148e.7 Erythromycin ethylsuccinate.

(a) *Requirements for certification*—(1) *Standards of identity, strength, quality, and purity.* Erythromycin ethylsuccinate is the white, odorless, crystalline ethylsuccinate ester of erythromycin. It is so purified and dried that:

(i) It contains not less than 765 micrograms of erythromycin per milligram, calculated on an anhydrous basis.

(ii) It is sterile.

(iii) It is nontoxic.

(iv) Its moisture content is not more than 3.0 percent.

(v) Its pH is not less than 6.0 and not more than 8.5.

(vi) Its residue on ignition is not more than 1.0 percent.

(vii) It gives a positive identity test for erythromycin ethylsuccinate.

(2) *Labeling*. It shall be labeled in accordance with the requirements of § 148.3(b) of this chapter. Its expiration date is 12 months.

(3) *Request for certification; samples*. In addition to the requirements of § 148.4 of this chapter, each such request shall contain:

(i) Results of tests and assays on the batch for potency, sterility, toxicity, moisture, pH, residue on ignition, identity, and crystallinity.

(ii) Samples required:

(*a*) For all tests except sterility: 10 packages, each containing approximately 500 milligrams.

(*b*) For sterility testing: 10 immediate containers.

(4) *Fees*. $4.00 for each package submitted in accordance with subparagraph (3)(ii)(*a*) of this paragraph; $10.00 for all immediate containers submitted in accordance with subparagraph (3)(ii)(*b*) of this paragraph.

(b) *Tests and methods of assay*—(1) *Potency*. Proceed as directed in § 148e.1(b)(1), except prepare the sample in the following manner: Dissolve approximately 50 milligrams, accurately weighed, in sufficient absolute methyl alcohol to give an estimated concentration of 1 milligram of erythromycin per milliliter. Further dilute in 0.1*M* potassium phosphate buffer, pH 8.0.

(2) *Sterility*. Using approximately 500 milligrams from each container tested, proceed as directed in § 141a.2 of this chapter, except that neither penicillinase nor the control tube is used in the test for bacteria.

(3) *Toxicity*. Proceed as directed in § 141d.305(b) of this chapter, except administer 0.5 milliliter of a suspension in sterile distilled water containing 80 milligrams of erythromycin per milliliter.

(4) *Moisture*. Proceed as directed in § 141a.26(e) of this chapter.

(5) *pH*. Proceed as directed in § 141a.5(b) of this chapter, using a 1.0 percent suspension in water.

(6) *Residue on ignition*. Proceed as directed in § 141e.401(g) of this chapter.

(7) *Identity*. Using a suitable spectrophotometer with 0.1-millimeter cells, scan the infrared absorption spectrum between 2 microns and 12.5 microns of a 5 percent chloroform solution of erythromycin ethylsuccinate. The absorption spectrum compares qualitatively to that of an authentic sample of erythromycin ethylsuccinate.

(8) *Crystallinity*. Proceed as directed in § 141a.5(c) of this chapter.

§ 148e.8 Erythromycin sulfate.

(a) *Requirements for certification*—(1) *Standards of identity, strength, quality, and purity*. Erythromycin sulfate is the sulfate salt of erythromycin. It is an odorless, practically white, crystalline powder. It is so purified and dried that:

(i) It contains not less than 840 micrograms of erythromycin per milligram, calculated on an anhydrous basis.

(ii) Its moisture content is not more than 7.0 percent.

(iii) Its pH in a solution containing 10 milligrams per milliliter is not less than 4.5 and not more than 6.5.

(iv) It gives a positive identity test for erythromycin sulfate.

(2) *Labeling*. It shall be labeled in accordance with the requirements of § 148.3(b) of this chapter. Its expiration date is 12 months.

(3) *Request for certification; samples*. In addition to the requirements of § 148.4 of this chapter, each such request shall contain:

(i) Results of tests and assays on the batch for potency, moisture, pH, crystallinity, and identity.

(ii) Samples required: 10 containers, each consisting of 300 milligrams.

(4) *Fees*. $4.00 for each container submitted in accordance with subparagraph (3)(ii) of this paragraph.

(b) *Tests and methods of assay*—(1) *Potency*. Proceed as directed in § 148e.1(b)(1), except prepare the sample in the following manner: Dissolve approximately 50 milligrams, accurately weighed, in sufficient absolute methyl alcohol to give a concentration of 1.0 milligram of erythromycin per milliliter.

(2) *Moisture*. Proceed as directed in § 141a.5(a) of this chapter.

(3) *pH*. Proceed as directed in § 141a.5(b) of this chapter, using a concentration of 10 milligrams per milliliter.

(4) *Identity*. Proceed as directed in § 148e.1(b)(8), except that its infrared absorbtion spectrum compares qualitatively to that of a similarly prepared authentic sample of erythromycin sulfate.

§ 148e.9 Erythromycin ethylsuccinate-sulfanilamide dental powder.

(a) *Requirements for certification*—(1) *Standards of identity, strength, quality, and purity*. Erythromycin ethylsuccinate-sulfanilamide dental powder is a dry mixture of crystalline erythromycin ethylsuccinate, sulfanilamide, and suitable and harmless flavorings. Each vial contains the equivalent of 10 milligrams of erythromycin and 250 milligrams of sulfanilamide. It is sterile. Its moisture content is not more than 1.0 percent. The crystalline erythromycin ethylsuccinate used conforms to the standards of § 148e.7(a)(1)(i), (iii), (iv), (v), (vi), and (vii). Each other ingredient used, if its name is recognized in the U.S.P. or N.F., conforms to the standards prescribed therefor by such official compendium.

(2) *Labeling*. It shall be labeled in accordance with the requirements of § 148.3 of this chapter. Its expiration date is 12 months.

(3) *Request for certification; samples*. In addition to the requirements of § 148.4 of this chapter, each such request shall contain:

(i) Results of tests and assays on:

(*a*) The erythromycin ethylsuccinate used in making the batch for potency, toxicity, moisture, pH, residue on ignition, identity, and crystallinity.

(*b*) The batch for potency, sterility, and moisture.

(ii) Samples required:

(*a*) The erythromycin ethylsuccinate used in making the batch: 10 containers, each consisting of 500 milligrams.

(*b*) The batch:

(*1*) For all tests except sterility: A minimum of 30 immediate containers.

(*2*) For sterility testing: 10 immediate containers.

(*c*) In case of an initial request for certification, each other ingredient used in making the batch: One immediate container of each containing 5 grams.

(4) *Fees*. $4.00 for each container submitted in accordance with subparagraph (3)(ii)(*a*) and (*c*) of this paragraph; $0.75 for each container submitted in accordance with subparagraph (3)(ii)(*b*)(*1*) of this paragraph; $10.00 for all containers submitted in accordance with subparagraph (3)(ii)(*b*)(*2*) of this paragraph.

(b) *Tests and methods of assay*—(1) *Potency*. Proceed as directed in § 148e.1(b)(1), using a representative number of immediate containers to prepare the sample for assay. Its potency is satisfactory if it contains not less than 90 percent and not more than 135 percent of the number of milligrams of erythromycin that it is represented to contain.

(2) *Sterility*. Use the entire contents of each container tested, and proceed as directed in § 141a.2 of this chapter, except that neither penicillinase nor the control tube is used in the test for bacteria.

(3) *Moisture*. Proceed as directed in § 141a.5(a) of this chapter.

§ 148e.10 Erythromycin ethylsuccinate granules for oral suspension.

(a) *Requirements for certification*—(1) *Standards of identity, strength, quality, and purity*. Erythromycin ethylsuccinate granules for oral suspension is a dry mixture of erythromycin ethylsuccinate, with suitable and harmless buffer substances, dispersing agents, diluents, colorings, and flavorings. It contains the equivalent of 40 milligrams of erythromycin per milliliter of the reconstituted suspension. Its moisture content is not more than 1 percent. When reconstituted as directed in the labeling, its pH is not less than 7.0 nor more than 9.0. The crystalline erythromycin ethylsuccinate used conforms to the standards prescribed by § 148e.7(a)(i), (iii), (iv), (v), (vi), and (vii). Each other ingredient used, if its name is recognized in the U.S.P. or N.F., conforms to the standards prescribed therefor by such official compendium.

(2) *Labeling*. It shall be labeled in accordance with the requirements of § 148.3 of this chapter. The expiration date is 12 months.

(3) *Request for certification; samples*. In addition to the requirements of § 148.4 of this chapter, each such request shall contain:

(i) Results of tests and assays on:

(*a*) The erythromycin ethylsuccinate used in making the batch for potency, toxicity, moisture, pH, residue on ignition, identity, and crystallinity.

(*b*) The batch, for potency, pH, and moisture.

(ii) Samples required:

(*a*) The erythromycin ethylsuccinte used in making the batch: 10 containers each consisting of approximately 500 milligrams.

(*b*) The batch: A minimum of 6 immediate containers.

(*c*) In case of an initial request for certification, each other ingredient used in making the batch: One package of each containing approximately 5 grams.

(4) *Fees.* $4.00 for each container submitted in accordance with subparagraph (3)(ii) of this paragraph.

(b) *Tests and methods of assay*—(1) *Potency.* Proceed as directed in § 148e.1 (b)(1), except prepare the sample in the following manner: Reconstitute the sample as directed in the labeling. Transfer 2 milliliters of the reconstituted suspension to a 200-milliliter volumetric flask, add absolute methyl alcohol to volume, and mix well. Further dilute with 0.1*M* potassium phosphate buffer, pH 8.0. Its potency is satisfactory if it contains not less than 90 percent nor more than 120 percent of the number of milligrams of erythromycin that it is represented to contain.

(2) *pH.* Proceed as directed in § 141a.5(b) of this chapter, using the suspension prepared as directed in the labeling.

(3) *Moisture.* Proceed as directed in § 141a.5(a) of this chapter.

§ 148e.11 Erythromycin ethylcarbonate for oral suspension.

(a) *Requirements for certification*—(1) *Standards of identity, strength, quality, and purity.* Erythromycin ethylcarbonate for oral suspension is a dry mixture of erythromycin ethylcarbonate, with suitable and harmless buffer substances, dispersing agents, diluents, colorings, and flavorings. It may contain suitable sulfonamides. The erythromycin ethylcarbonate content is not less than 40 milligrams of erythromycin per milliliter of the reconstituted suspension. Its moisture content is not more than 2.0 percent. When reconstituted as directed in the labeling, its pH is not less than 6.4 and not more than 7.0. The erythromycin ethylcarbonate used conforms to the standards prescribed by § 148e.2 (a)(1). Each other substance used, if its name is recognized in the U.S.P. or N.F., conforms to the standards prescribed therefor by such official compendium.

(2) *Labeling.* It shall be labeled in accordance with the requirements of § 148.3 of this chapter. Its expiration date is 12 months.

(3) *Request for certification; samples.* In addition to the requirements of § 148.4 of this chapter, each such request shall contain:

(i) Results of tests and assays on:

(*a*) Erythromycin ethylcarbonate used in making the batch for potency, toxicity, moisture, pH, crystallinity, and identity.

(*b*) The batch for potency, moisture, and pH.

(ii) Samples required:

(*a*) Erythromycin ethylcarbonate used in making the batch: 10 containers, each containing 500 milligrams.

(*b*) The batch: A minimum of 6 immediate containers.

(*c*) In case of an initial request for certification, each other ingredient used in making the batch: One container of each, consisting of 5 grams.

(4) *Fees.* $4.00 for each container submitted in accordance with subparagraph (3)(ii) of this paragraph.

(b) *Tests and methods of assay*—(1) *Potency.* Proceed as directed in § 148e.2 (b)(1), except prepare the sample in the following manner: Reconstitute the suspension as directed in the labeling. Place an aliquot (usually a single dose) of an accurately measured volume of the oral suspension in a 100-milliliter volumetric flask and dissolve in 40 milliliters of reagent-grade methyl alcohol. Bring to volume with distilled water and mix well. Hydrolyze either in a 60° C. water bath for 3 hours or keep at room temperature for 40 hours to 48 hours. Make subsequent dilutions in 0.1*M* potassium phosphate buffer, pH 8.0. The erythromycin ethylcarbonate content is satisfactory if it is not less than 90 percent and not more than 115 percent of the number of milligrams of erythromycin that it is represented to contain.

(2) *Moisture.* Proceed as directed in § 141a.26(e) of this chapter.

(3) *pH.* Proceed as directed in § 141a.5 (b) of this chapter, using the suspension prepared as directed in its labeling.

§ 148e.12 Erythromycin estolate for oral suspension.

(a) *Requirements for certification*—(1) *Standards of identity, strength, quality, and purity.* Erythromycin estolate for oral suspension is a dry mixture of erythromycin estolate, with suitable and harmless buffer substances, dispersing agents, diluents, colorings, and flavorings. It may contain suitable sulfonamides. The erythromycin estolate content is 25 milligrams of erythromycin per milliliter of the reconstituted suspension. When reconstituted as directed in its labeling, its pH is not less than 5.0 and not more than 7.0. Its moisture content is not more than 2.0 percent. The erythromycin estolate used conforms to the standards of § 148e.5(a)(1). Each other substance used, if its name is recognized in the U.S.P. or N.F., conforms to the standards prescribed therefor by such official compendium.

(2) *Labeling.* It shall be labeled in accordance with the requirements of § 148.3 of this chapter. Its expiration date is 12 months.

(3) *Request for certification; samples.* In addition to the requirements of § 148.4 of this chapter, each such request shall contain:

(i) Results of tests and assays on:

(*a*) The erythromycin estolate used in making the batch for potency, toxicity, moisture, pH, crystallinity, and identity.

(*b*) The batch: Potency, moisture, and pH.

(ii) Samples required:

(*a*) The erythromycin estolate used in making the batch: 10 immediate containers, each consisting of 300 milligrams.

(*b*) The batch: A minimum of 6 immediate containers.

(*c*) In case of an initial request for certification, each other ingredient used in making the batch: One container of each, consisting of 5 grams.

(4) *Fees.* $4.00 for each container submitted in accordance with subparagraph (3)(ii) of this paragraph.

(b) *Tests and methods of assay*—(1) *Potency.* Proceed as directed in § 148e.5 (b)(1), except prepare the sample in the following manner: Reconstitute the suspension as directed in the labeling. Place an accurately measured aliquot (usually a single dose) of the well-shaken suspension in a 100-milliliter volumetric flask and dissolve with 40 milliliters of reagent-grade methyl alcohol. Bring to volume with 0.1*M* potassium phosphate buffer, pH 8.0, and mix well. Hydrolyze at 60° C. for 2 hours or at room temperature for 16 hours to 18 hours.

The erythromycin estolate content is satisfactory if it is not less than 90 percent nor more than 115 percent of the number of milligrams of erythromycin that it is represented to contain.

(2) *Moisture.* Proceed as directed in § 141a.26(e) of this chapter, using the dry powder.

(3) *pH.* Proceed as directed in § 141a.5(b) of this chapter, using the drug reconstituted as directed in its labeling.

§ 148e.13 Erythromycin ethylsuccinate oral suspension.

(a) *Requirements for certification*—(1) *Standards of identity, strength, quality, and purity.* Erythromycin ethylsuccinate oral suspension is erythromycin ethylsuccinate, with suitable and harmless buffer substances, dispersing agents, colorings, and flavorings suspended in peanut oil and glycerin. It contains the equivalent of not less than 40 milligrams of erythromycin per milliliter. Its moisture content is not more than 5.0 percent. The crystalline erythromycin ethylsuccinate used conforms to the standards prescribed by § 148e.7(a)(1) (i), (iii), (iv), (v), (vi), and (vii). Each other substance used, if its name is recognized in the U.S.P. or N.F., conforms to the standards prescribed therefor by such official compendium.

(2) *Labeling.* It shall be labeled in accordance with the requirements of § 148.3 of this chapter. Its expiration date is 12 months.

(3) *Request for certification; samples.* In addition to the requirement of § 148.4 of this chapter, each such request shall contain:

(i) Results of tests and assays on:

(*a*) The erythromycin ethylsuccinate used in making the batch for potency, toxicity, moisture, pH, identity, residues on ignition, and crystallinity.

(*b*) The batch for potency and moisture:

(ii) Samples required:

(*a*) The erythromycin ethylsuccinate used in making the batch: 10 containers, each consisting of 500 milligrams.

(*b*) The batch: A minimum of 5 immediate containers.

(*c*) In case of an initial request for certification, each other ingredient used in making the batch: One container of each, consisting of 5 grams.

(4) *Fees.* $4.00 for each container submitted in accordance with subparagraph (3) (ii) of this paragraph.

(b) *Tests and methods of assay*—(1) *Potency.* Proceed as directed in § 148e.1 (b) (1), except prepare the sample in the following manner: by means of a syringe, transfer 2 milliliters of the sample to a 100-milliliter volumetric flask. Add absolute methyl alcohol to volume, and mix well. Further dilute with 0.1*M* potassium phosphate buffer, pH 8.0. Its potency is satisfactory if it contains not less than 90 percent and not more than 115 percent of the number of milligrams of erythromycin that it is represented to contain.

(2) *Moisture.* Proceed as directed in § 141a.8(b) of this chapter.

§ 148e.14 Erythromycin ointment.

(a) *Requirements for certification*—(1) *Standards of identity, strength, quality, and purity.* Erythromycin ointment is erythromycin in a suitable and harmless ointment base. It may contain suitable preservatives. Each gram of ointment contains 10 milligrams of erythromycin. The moisture content is not more than 1.0 percent. The erythromycin used conforms to the standards prescribed by § 148e.1(a)(1) (i), (iii), (iv), (v), and (vii). Each other substance used, if its name is recognized in the U.S.P. or N.F., conforms to the standards prescribed therefor by such official compendium.

(2) *Labeling.* It shall be labeled in accordance with the requirements of § 148.3 of this chapter. Its expiration date is 12 months.

(3) *Request for certification; samples.* In addition to the requirements of § 148.4 of this chapter, each such request shall contain:

(i) Results of tests and assays on:

(*a*) The erythromycin used in making the batch for potency, pH, moisture, residue on ignition, crystallinity, and identity.

(*b*) The batch for potency and moisture.

(ii) Samples required:

(*a*) The erythromycin used in making the batch: 10 packages, each containing not less than 500 milligrams.

(*b*) The batch: A minimum of 5 immediate containers.

(*c*) In case of an initial request for certification, each other ingredient used in making the batch: One package of each, consisting of not less than 5 grams.

(4) *Fees.* $4.00 for each immediate container or package submitted in accordance with subparagraph (3)(ii) of this paragraph.

(b) *Tests and methods of assay*—(1) *Potency.* Proceed as directed in § 148e.1 (b) (1), except prepare the sample by any one of the following procedures:

(i) Place 1 gram of the ointment, accurately weighed, in a 1-liter volumetric flask, add 50 milliliters of peroxide-free ether, and shake until dissolved. Add 200 milliliters of absolute methyl alcohol, and mix thoroughly. Fill to volume and further dilute to the reference point with 0.1*M* potassium phosphate buffer, pH 8.0.

(ii) Place 1 gram of the ointment, accurately weighed, in a 250-milliliter separatory funnel containing 50 milliliters of reagent-grade petroleum ether. Shake until dissolved. Wash with four separate washings of a 4:1 mixture of reagent-grade methyl alcohol and distilled water. Combine the washings and bring to volume with the methyl alcohol-water solution in a volumetric flask. Further dilute to the reference point in 0.1*M* potassium phosphate buffer, pH 8.0.

(iii) Place 1 gram of the ointment, accurately weighed, in a high-speed blender with 100 milliliters of polyethylene glycol 400, and blend for 3 minutes. Filter through a cotton plug or filter paper and further dilute in 0.1*M* potassium phosphate buffer, pH 8.0.

Its potency is satisfactory if it contains not less than 90 percent and not more than 125 percent of the number of milligrams of erythromycin that it is represented to contain.

(2) *Moisture.* Proceed as directed in § 141a.8(b) of this chapter.

§ 148e.15 Erythromycin-neomycin sulfate ointment.

(a) *Requirements for certification*—(1) *Standards of identity, strength, quality, and purity.* Erythromycin-neomycin sulfate ointment is erythromycin and neomycin sulfate with a suitable emollient and preservatives, in a suitable and harmless ointment base. Each gram contains 5 milligrams of erythromycin and 3.5 milligrams of neomycin. The moisture content is not more than 1 percent. The erythromycin used conforms to the standards prescribed therefor by § 148e.1(a)(1) (i), (iii), (iv), (v), and (vii). The neomycin sulfate used conforms to the standards prescribed in § 148i.1(a)(1) (i), (vi) (vii), and (viii) of this chapter. Each other substance used, if its name is recognized in the U.S.P. or N.F., conforms to the standards prescribed therefor by such official compendium.

(2) *Labeling.* It shall be labeled in accordance with the requirements of § 148.3 of this chapter. Its expiration date is 12 months.

(3) *Request for certification; samples.* In addition to the requirements of § 148.4 of this chapter, each such request shall contain:

(i) Results of tests and assays on:

(*a*) The erythromycin used in making the batch for potency, pH, moisture, residue on ignition, crystallinity, and identity.

(*b*) The neomycin sulfate used in making the batch for potency, pH, moisture, and identity.

(*c*) The batch for erythromycin content, neomycin content, and moisture.

(ii) Samples required:

(*a*) The erythromycin used in making the batch: 10 packages, each containing not less than 500 milligrams.

(*b*) The neomycin sulfate used in making the batch: 10 packages, each containing not less than 300 milligrams.

(*c*) The batch: A minimum of 6 immediate containers.

(*d*) In case of an initial request for certification, each other ingredient used in making the batch: One package of each containing not less than 5 grams.

(4) *Fees.* $4.00 for each package submitted in accordance with subparagraph (3)(ii) (*a*), (*b*), and (*d*) of this paragraph; $5.00 for each container submitted in accordance with subparagraph (3)(ii)(*c*) of this paragraph.

(b) *Tests and methods of assay*—(1) *Potency*—(i) *Erythromycin content.* Proceed as directed in § 148e.14(b)(1)(iii). Its erythromycin content is satisfactory if it is not less than 90 percent and not more than 125 percent of the number of milligrams of erythromycin that it is represented to contain.

(ii) *Neomycin content.* Proceed as directed in § 148i.3(b)(1) of this chapter, except that after the extraction has been completed and the volume adjusted, place the buffer solution in a second separatory funnel and wash with three 30-milliliter portions of peroxide-free ether. Discard the ether washes. Its neomycin content is satisfactory if it is not less than 90 percent and not more than 125 percent of the number of milligrams of neomycin that it is represented to contain.

(2) *Moisture.* Proceed as directed in § 141a.8(b) of this chapter.

§ 148e.16 Erythromycin-polymyxin B sulfate ophthalmic ointment.

(a) *Requirements for certification*—(1) *Standards of identity, strength, quality, and purity.* Erythromycin-polymyxin B sulfate ophthalmic ointment is erythromycin and polymyxin B sulfate in a suitable and harmless ointment base. Each gram contains 5 milligrams of erythromycin and 10,000 units of polymyxin B. The moisture content is not more than 1 percent. The crystalline erythromycin used conforms to the standards prescribed therefor by § 148e.1(a)(1) (i), (iii), (iv), (v), and (vii). The polymyxin B sulfate used conforms to the standards prescribed by § 148p.1(a)(1) (i), (v), (vi), (vii), and (ix) of this chapter. Each other substance used, if its name is recognized in the U.S.P. or N.F., conforms to the standards prescribed therefor by such official compendium.

(2) *Labeling.* It shall be labeled in accordance with the requirements of § 148.3 of this chapter. Its expiration date is 12 months.

(3) *Request for certification; samples.* In addition to the requirements of § 148.4 of this chapter, each such request shall contain:

(i) Results of tests and assays on:

(*a*) The erythromycin used in making the batch for potency, pH, moisture, residue on ignition, crystallinity, and identity.

(*b*) The polymyxin B sulfate used in making the batch for potency, pH, moisture, and identity.

(*c*) The batch for erythromycin content, polymyxin B content, and moisture.

(ii) Samples required:

(*a*) The erythromycin used in making the batch: 10 packages, each containing not less than 500 milligrams.

(*b*) The polymyxin B sulfate used in making the batch: 10 packages, each containing not less than 300 milligrams.

(*c*) The batch: Six immediate containers.

(*d*) In case of an initial request for certification, each other ingredient used in making the batch: One package of each, containing 5 grams.

(4) *Fees.* $4.00 for each package in the samples submitted in accordance with subparagraph (3) (ii) (*a*), (*b*), and (*d*) of this paragraph; $5.00 for each container submitted in accordance with subparagraph (3) (ii) (*c*) of this paragraph.

(b) *Tests and methods of assay*—(1) *Potency*—(i) *Erythromycin content.* Proceed as directed in § 148e.14(b) (1). The erythromycin content is satisfactory if it is not less than 90 percent and not more than 125 percent of the number of milligrams of erythromycin that it is represented to contain.

(ii) *Polymyxin B content.* Proceed as directed in § 148p.3(b) (1) of this chapter. The polymyxin B content is satisfactory if it is not less than 90 percent and not more than 125 percent of the number of units of polymyxin B that it is represented to contain.

(2) *Moisture.* Proceed as directed in § 141a.8(b) of this chapter.

§ 148e.17 Erythromycin estolate capsules.

(a) *Requirements for certification*—(1) *Standards of identity, strength, quality, and purity.* Erythromycin estolate capsules are capsules containing erythromycin estolate, with suitable and harmless buffer substances and diluents, enclosed in a gelatin capsule. The erythromycin estolate content of each capsule is equivalent to either 250 milligrams of erythromycin or 125 milligrams of erythromycin. The moisture content is not more than 5 percent. The erythromycin estolate used conforms to the standards prescribed therefor by § 148e.5(a) (1). Each other substance used, if its name is recognized in the U.S.P. or N.F., conforms to the standards prescribed therefor by such official compendium.

(2) *Labeling.* It shall be labeled in accordance with the requirements of § 148.3 of this chapter. Its expiration date is 12 months.

(3) *Request for certification; samples.* In addition to the requirements of § 148.4 of this chapter, each such request shall contain:

(i) Results of tests and assays on:

(*a*) The erythromycin estolate used in making the batch for potency, toxicity, pH, moisture, crystallinity, and identity.

(*b*) The batch for potency and moisture.

(ii) Samples required:

(*a*) The erythromycin estolate used in making the batch: 10 packages, each containing not less than 300 milligrams.

(*b*) The batch: A minimum of 30 capsules.

(*c*) In case of an initial request for certification, each other ingredient used: One package of each containing not less than 5 grams.

(4) *Fees.* $4.00 for each package submitted in accordance with subparagraph (3) (ii) (*a*) and (*c*) of this paragraph; $0.75 for each capsule submitted in accordance with subparagraph (3) (ii) (*b*) of this paragraph.

(b) *Tests and methods of assay*—(1) *Potency.* Proceed as directed in § 148e.5 (b) (1), except prepare the sample in the following manner: Using 200 milliliters of reagent-grade methyl alcohol and 300 milliliters of 0.1*M* potassium phosphate buffer, pH 8.0, blend a representative number of capsules in a high-speed glass blender for 2 to 3 minutes. The erythromycin content is satisfactory if it is not less than 90 percent and not more than 115 percent of the number of milligrams of erythromycin that it is represented to contain.

(2) *Moisture.* Proceed as directed in § 141a.26(e) of this chapter.

§ 148e.19 Erythromycin gluceptate dental cones.

(a) *Requirements for certification*—(1) *Standards of identity, strength, quality, and purity.* Erythromycin gluceptate dental cones are composed of erythromycin gluceptate and suitable and harmless binders and diluents. The erythromycin gluceptate content of each cone is equivalent to 5 milligrams of erythromycin. The moisture content is not more than 1.5 percent. The crystalline erythromycin gluceptate used conforms to the standards prescribed by § 148e.3(a) (1) (i), (iii), (v), (vi), and (vii). Each other ingredient used, if its name is recognized in the U.S.P. or N.F., conforms to the standards prescribed therefor by such official compendium.

(2) *Labeling.* It shall be labeled in accordance with the requirements of § 148.3 of this chapter. Its expiration date is 12 months.

(3) *Request for certification; samples.* In addition to the requirements of § 148.4 of this chapter, each such request shall contain:

(i) Results of tests and assays on:

(*a*) The erythromycin gluceptate used, for potency, toxicity, moisture, pH, and identity.

(*b*) The batch for potency and moisture.

(ii) Samples required:

(*a*) The erythromycin gluceptate used: 10 packages, each containing 300 milligrams.

(*b*) The batch: A minimum of 30 cones.

(*c*) In case of an initial request for certification, each other ingredient used: One package of each, containing 5 grams.

(4) *Fees.* $4.00 for each package submitted in accordance with subparagraph (3) (ii) (*a*) and (*c*) of this paragraph; $0.75 for each cone submitted in accordance with subparagraph (3) (ii) (*b*) of this paragraph.

(b) *Tests and methods of assay*—(1) *Potency.* Proceed as directed in § 148e.3(b) (1), except prepare the sample as follows: Blend a representative number of cones in a high-speed glass blender with 500 milliliters of 0.1*M* potassium phosphate buffer, pH 8.0. The erythromycin gluceptate content is satisfactory if it is not less than 90 percent nor more than 135 percent of the number of milligrams of erythromycin that it is represented to contain.

(2) *Moisture.* Proceed as directed in § 141a.26(e) of this chapter.

§ 148e.20 Erythromycin gluceptate-polymyxin B sulfate-benzocaine for otic solution.

(a) *Requirements for certification*—(1) *Standards of identity, strength, quality, and purity.* Erythromycin gluceptate-polymyxin B sulfate-benzocaine for otic solution is a packaged combination of one immediate container of dry erythromycin gluceptate powder and one immediate container of polymyxin B sulfate and benzocaine, dissolved in propylene glycol. When reconstituted as directed in its labeling, each milliliter contains the equivalent of 5 milligrams of erythromycin, 10,000 units of polymyxin B, and 50 milligrams of benzocaine. The moisture content of the dry powder is not more than 5.0 percent. The moisture content of the diluting fluid is not more than 1.5 percent. The erythromycin gluceptate used conforms to the standards prescribed by § 148e.3 (a) (1) (i), (v), (vi), and (vii). The polymyxin B sulfate used conforms to the standards prescribed by § 148p.1(a) (1) (i), (v), (vi), (vii), and (ix) of this chapter. Each other ingredient used, if its name is recognized in the U.S.P. or N.F., conforms to the standards prescribed therefore by such official compendium.

(2) *Labeling.* It shall be labeled in accordance with the requirements of § 148.3 of this chapter. Its expiration date is 12 months.

(3) *Request for certification; samples.* In addition to the requirements of § 148.4 of this chapter, each such request shall contain:

(i) Results of tests and assays on:

(*a*) The erythromycin gluceptate used in making the batch, for potency, moisture, pH, and identity.

(*b*) The polymyxin B sulfate used in making the batch, for potency, moisture, pH, residue on ignition, and identity.

(*c*) The batch for erythromycin content, polymyxin B content, moisture content of the erythromycin gluceptate dry powder, and moisture content of the diluting fluid.

(ii) Samples required:

(*a*) The erythromycin gluceptate used in making the batch: 10 packages, each consisting of not less than 300 milligrams.

(*b*) The polymyxin B sulfate used in making the batch: 10 packages, each consisting of not less than 300 milligrams.

(*c*) The batch:

(*1*) For all tests except moisture: A minimum of 6 combined packages.

(*2*) For moisture content: A minimum of 8 combined packages.

(*d*) In case of an initial request for certification, each other ingredient used: One package consisting of not less than 5 grams.

(4) *Fees.* $4.00 for each package submitted in accordance with subparagraph (3) (ii) of this paragraph.

(b) *Tests and methods of assay*—(1) *Potency*—(i) *Erythromycin content.* Proceed as directed in § 148e.3(b) (1), using the entire contents of each vial of erythromycin gluceptate. The erythromycin content is satisfactory if it contains not less than 90 percent and not more than 125 percent of the number of milligrams of erythromycin that it is represented to contain.

(ii) *Polymyxin B content.* By means of a needle and syringe, withdraw a representative aliquot of the diluting fluid, and proceed as directed in § 148p.1(b)(1) of this chapter. The polymyxin B content is satisfactory if it contains not less than 90 percent and not more than 125 percent of the number of units of polymyxin B that it is represented to contain.

(2) *Moisture*—(i) *Erythromycin gluceptate vial.* Proceed as directed in § 141a.26(e) of this chapter, using the erythromycin gluceptate dry powder.

(ii) *Polymyxin B diluting fluid.* Proceed as directed in § 141a.8(b) of this chapter, using the diluting fluid without reconstitution.

§ 148e.21 Erythromycin sulfate-polymyxin B sulfate-pramoxine hydrochloride otic solution.

(a) *Requirements for certification*—(1) *Standards of identity, strength, quality, and purity.* Erythromycin sulfate-polymyxin B sulfate-pramoxine hydrochloride otic solution is erythromycin sulfate, polymyxin B sulfate, and pramoxine hydrochloride dissolved in a suitable and harmless vehicle. Each milliliter contains the equivalent of 5 milligrams of erythromycin, 10,000 units of polymyxin B sulfate, and 10 milligrams of pramoxine hydrochloride. It contains not more than 1.5 percent moisture. The erythromycin sulfate used conforms to the standards prescribed by § 148e.8(a)(1). The polymyxin B sulfate used conforms to the standards prescribed by § 148p.1(a)(1) (i), (v), (vi), (vii), and (ix) of this chapter. Each other substance used, if its name is recognized in the U.S.P. or N.F., conforms to the standards prescribed therefor by such official compendium.

(2) *Labeling.* It shall be labeled in accordance with the requirements of § 148.3 of this chapter. Its expiration date is 12 months.

(3) *Request for certification; samples.* In addition to the requirements of § 148.4 of this chapter, each such request shall contain:

(i) Results of tests and assays on:

(*a*) The erythromycin sulfate used in making the batch for potency, moisture, pH, identity, and crystallinity.

(*b*) The polymyxin B sulfate used in making the batch for potency, moisture, pH, residue on ignition, and identity.

(*c*) The batch for erythromycin content, polymyxin B content, and moisture.

(ii) Samples required:

(*a*) The erythromycin sulfate used in making the batch: 10 packages, each consisting of 300 milligrams.

(*b*) The polymyxin B sulfate used in making the batch: 10 packages, each consisting of 300 milligrams.

(*c*) The batch: A minimum of 6 immediate containers.

(*d*) In case of an initial request for certification, each other ingredient used in making the batch: 1 container of each, containing not less than 5 grams.

(4) *Fees.* $4.00 for each container submitted in accordance with subparagraph (3)(ii) (*a*), (*b*), and (*d*) of this paragraph; $5.00 for each container submitted in accordance with subparagraph (3)(ii)(*c*) of this paragraph.

(b) *Tests and methods of assay*—(1) *Potency*—(i) *Erythromycin content.* Proceed as directed in § 148e.1(b)(1), using a 1.0 milliliter aliquot of the solution. The erythromycin sulfate content is satisfactory if it contains not less than 90 percent and not more than 135 percent of the number of milligrams of erythromycin that it is represented to contain.

(ii) *Polymyxin B content.* Proceed as directed in § 148p.1(b)(1) of this chapter, using a 1.0-milliliter aliquot of the solution. The polymyxin B content is satisfactory if it contains not less than 90 percent and not more than 135 percent of the number of units of polymyxin B that it is represented to contain.

(2) *Moisture.* Proceed as directed in § 141a.8(b) of this chapter.

§ 148e.22 Erythromycin estolate for pediatric drops.

(a) *Requirements for certification*—(1) *Standards of identity, strength, quality, and purity.* Erythromycin estolate for pediatric drops is a dry mixture of erythromycin estolate, with suitable and harmless dispersing agents, buffer substances, diluents, colorings, and flavorings. When reconstituted as directed in the labeling, each milliliter contains the equivalent of 100 milligrams of erythromycin. Its moisture content is not more than 2.0 percent. Its pH is not less than 5.0 nor more than 5.5. The erythromycin estolate used conforms to the standards prescribed by § 148e.5(a)(1). Each other ingredient used, if its name is recognized in the U.S.P. or the N.F., conforms with the standards prescribed therefor by such official compendium.

(2) *Labeling.* It shall be labeled in accordance with the requirements of § 148.3 of this chapter. Its expiration date is 12 months.

(3) *Request for certification; samples.* In addition to the requirements of § 148.4 of this chapter, each such request shall contain:

(i) Results of tests and assays on:

(*a*) The erythromycin estolate used in making the batch for potency, toxicity, pH, moisture, crystallinity, and identity.

(*b*) The batch for potency, moisture, and pH.

(ii) Samples required:

(*a*) The erythromycin estolate used in making the batch: 10 packages, each containing not less than 300 milligrams.

(*b*) The batch: A minimum of 5 immediate containers.

(*c*) In case of an initial request for certification, each other ingredient used in making the batch: One package of each, consisting of not less than 5 grams.

(4) *Fees.* $4.00 for each package or immediate container in the sample submitted in accordance with subparagraph (3)(ii) of this paragraph.

(b) *Tests and methods of assay*—(1) *Potency.* Proceed as directed in § 148e.12(b)(1). Its potency is satisfactory if it contains not less than 90 percent nor more than 115 percent of the number of milligrams of erythromycin that it is represented to contain.

(2) *Moisture.* Proceed as directed in § 141a.26(e) of this chapter.

(3) *pH.* Proceed as directed in § 141a.5(b) of this chapter, using the suspension prepared as directed in the labeling.

§ 148e.23 [Reserved]

§ 148e.24 Erythromycin enteric-coated tablets.

(a) *Requirements for certification*—(1) *Standards of identity, strength, quality, and purity.* Erythromycin enteric-coated tablets are enteric-coated tablets composed of erythromycin, suitable and harmless buffer substances, diluents, binders, lubricants, colorings, and flavorings. It may contain suitable sulfonamides. The potency of each tablet is 100 milligrams of erythromycin or 250 milligrams of erythromycin. Each tablet shall meet the tests for enteric-coated tablets set forth in the U.S.P. and shall disintegrate within a total time of 2 hours. The moisture content is not more than 6 percent. The erythromycin base used in making the batch conforms to the standards of § 148e.1(a)(1) (i), (ii), (iii), (iv), (v), and (vii). Each other substance used, if its name is recognized in the U.S.P. or N.F., conforms to the standards prescribed therefor by such official compendium.

(2) *Labeling.* It shall be labeled in accordance with the requirements of § 148.3 of this chapter. Its expiration date is 12 months.

(3) *Request for certification; samples.* In addition to the requirements of § 148.4 of this chapter, each such request shall contain:

(i) Results of tests and assays on:

(*a*) The erythromycin used in making the batch for potency, toxicity, moisture, pH, residue on ignition, crystallinity, and identity.

(*b*) The batch for potency, moisture, and disintegration time.

(ii) Samples required:

(*a*) The erythromycin used in making the batch: 10 packages, each containing 500 milligrams.

(*b*) The batch:

(*1*) For all tests except disintegration time: A minimum of 30 tablets.

(*2*) For disintegration time: 6 tablets.

(*c*) In case of an initial request for certification, each other ingredient used in making the batch: One package of each, containing not less than 5 grams.

(4) *Fees.* $4.00 for each package submitted in accordance with subparagraph (3)(ii) (*a*) and (*c*) of this paragraph; $0.75 for each tablet submitted in accordance with subparagraph (3)(ii)(*b*)(*1*) of this paragraph; $3.00 for all tablets submitted in accordance with subparagraph (3)(ii)(*b*)(*2*) of this paragraph.

(b) *Tests and methods of assay*—(1) *Potency.* Proceed as directed in § 148e.26(b)(1). The erythromycin content is satisfactory if it is not less than 90 percent nor more than 120 percent of the number of milligrams of erythromycin that it is represented to contain.

(2) *Moisture.* Proceed as directed in § 141a.26(e) of this chapter.

(3) *Disintegration time.* Proceed as directed in the U.S.P. for enteric-coated tablets.

§ 148e.25 Erythromycin lactobionate for intravenous infusion.

(a) *Requirements for certification*—(1) *Standards of identity, strength, quality, and purity.* Erythromycin lactobionate for intravenous infusion is a dry mixture of erythromycin lactobionate and a suitable preservative. It contains the equivalent of either 300 milligrams of erythromycin or 1 gram of erythromycin per vial. It is sterile. It is nonpyrogenic. Its is nontoxic. Its moisture content is not more than 5 percent. Its pH is not less than 6.5 and not more than 7.5. The erythromycin used conforms to the standards prescribed by § 148e.1(a)(1) (i), (iii), (iv), (v), and (vi). Each other substance used, if its name is recognized in the U.S.P. or N.F., conforms to the standards prescribed therefor by such official compendium.

(2) *Labeling.* It shall be labeled in accordance with the requirements of § 148.3 of this chapter. Its expiration date is 12 months.

(3) *Request for certification; samples.* In addition to the requirements of §148.4 of this chapter, each such request shall contain:

(i) Results of tests and assays on:

(*a*) The erythromycin used in making the batch for potency, pH, moisture, residue on ignition, heavy metals, and crystallinity.

(*b*) The batch for potency, sterility, pyrogens, toxicity, moisture, pH, and identity.

(ii) Samples required:

(*a*) The erythromycin used in making the batch: 10 containers, each consisting of not less than 500 milligrams.

(*b*) The batch:

(*1*) For all tests except sterility: A minimum of 10 immediate containers.

(*2*) For sterility testing: 10 immediate containers.

(*c*) In case of an initial request for certification, each other ingredient used in making the batch: One container of each, consisting of not less than 5 grams.

(4) *Fees.* $4.00 for each container submitted in accordance with subparagraph (3)(ii) (*a*) and (*c*) of this paragraph; $5.00 for each immediate container submitted in accordance with subparagraph (3)(ii)(*b*)(*1*) of this paragraph; $10.00 for all containers submitted in accordance with subparagraph (3)(ii)(*b*)(*2*) of this paragraph.

(b) *Tests and methods of assay*—(1) *Potency.* Dissolve the entire contents of the vial in sufficient distilled water to give a concentration of 10 milligrams of erythromycin per milliliter (estimated). Proceed as directed in § 148e.1(b)(1). The erythromycin lactobionate content is satisfactory if it is not less than 90 percent nor more than 120 percent of the number of milligrams of erythromycin that it is represented to contain.

(2) *Sterility.* Use the entire contents or not more than 500 milligrams from each container tested, and proceed as directed in § 141a.2 of this chapter, except that neither penicillinase nor the control tube is used in the test for bacteria.

(3) *Pyrogens.* Proceed as directed in § 141a.3 of this chapter, using as a test dose 1 milliliter per kilogram of a solution in sterile, pyrogen-free distilled water containing 30 milligrams of erythromycin per milliliter.

(4) *Toxicity.* Proceed as directed in § 141a.4 of this chapter, using as a test dose 0.5 milliliter of a solution in sterile distilled water containing 3 milligrams of erythromycin per milliliter.

(5) *Moisture.* Proceed as directed in § 141a.26(e) of this chapter.

(6) *pH.* Proceed as directed in § 141a.5(b) of this chapter, using a concentration of 50 milligrams of erythromycin per milliliter.

(7) *Identity.* The infrared absorption spectrum between 2 microns and 12 microns of a liquid petrolatum dispersion compares qualitatively to that of a similarly prepared authentic erythromycin lactobionate sample.

§ 148e.26 Erythromycin tablets.

(a) *Requirements for certification*—(1) *Standards of identity, strength, quality, and purity.* Erythromycin tablets are erythromycin, with suitable and harmless buffer substances, diluents, binders, lubricants, colorings, and flavorings, and suitable preservatives. It may contain suitable sulfonamides. The potency of each tablet is 75 milligrams, or 100 milligrams, or 250 milligrams of erythromycin. Tablets shall disintegrate within 1 hour. The moisture content is not more than 7.5 percent. The erythromycin used in making the batch conforms to the standards prescribed by § 148e.1(a)(1) (i), (ii), (iii), (iv), (v), and (vii). Each other substance used, if its name is recognized in the U.S.P. or N.F., conforms to the standards prescribed therefor by such official compendium.

(2) *Labeling.* It shall be labeled in accordance with the requirements of § 148.3 of this chapter. Its expiration date is 12 months.

(3) *Request for certification; samples.* In addition to the requirements of § 148.4 of this chapter, each such request shall contain:

(i) Results of tests and assays on:

(*a*) The erythromycin used in making the batch for potency, toxicity, pH, moisture, residue on ignition, crystallinity, and identity.

(*b*) The batch for potency, disintegration time, and moisture.

(ii) Samples required:

(*a*) The erythromycin used in making the batch: 10 packages, each containing 500 milligrams.

(*b*) The batch:

(*1*) For all tests except disintegration time: A minimum of 30 tablets.

(*2*) For disintegration time: 6 tablets.

(*c*) In case of an initial request for certification, each other ingredient used in making the batch: 1 package, of each, containing not less than 5 grams.

(4) *Fees.* $0.75 for each tablet submitted in accordance with subparagraph (3)(ii)(*b*)(*1*) of this paragraph; $3.00 for all tablets submitted in accordance with subparagraph (3)(ii)(*b*)(*2*) of this paragraph; $4.00 for each package submitted in accordance with subparagraph (3)(ii) (*a*) and (*c*) of this paragraph.

(b) *Tests and methods of assay*—(1) *Potency.* Proceed as directed in § 148e.1 (b)(1), except prepare the sample in the following manner: Blend a representative number of tablets in a high-speed glass blender with 100 milliliters of absolute methyl alcohol. Add 400 milliliters of 0.1*M* potassium phosphate buffer, pH 8.0, and blend again for 2 to 3 minutes. The erythromycin base content is satisfactory if it is not less than 90 percent and not more than 120 percent of the number of milligrams that it is represented to contain.

(2) *Moisture.* Proceed as directed in § 141a.26(e) of this chapter.

(3) *Disintegration time.* Proceed as directed in § 141a.9(c)(2) of this chapter.

§ 148e.27 Erythromycin stearate tablets.

(a) *Requirements for certification*—(1) *Standards of identity, strength, quality, and purity.* Erythromycin stearate tablets are tablets composed of erythromycin stearate, with suitable and harmless buffer substances, diluents, binders, lubricants, colorings, and flavorings. It may contain suitable sulfonamides. The potency of each tablet is 75 milligrams, or 100 milligrams, or 125 milligrams, or 250 milligrams of erythromycin. Tablets shall disintegrate within 1½ hours, except tablets containing sulfonamides shall disintegrate within 2½ hours. The moisture content is not more than 7 percent. The erythromycin stearate used in making the tablets conforms to the standards prescribed by § 148e.6 (a)(1). Each other substance used, if its name is recognized in the U.S.P. or N.F., conforms to the standards prescribed therefor by such official compendium.

(2) *Labeling.* It shall be labeled in accordance with the requirements of § 148.3 of this chapter. Its expiration date is 12 months.

(3) *Request for certification; samples.* In addition to the requirements of § 148.4 of this chapter, each such request shall contain:

(i) Results of tests and assays on:

(*a*) The erythromycin stearate used in making the batch for potency, toxicity, pH, moisture, residue on ignition, crystallinity, and identity.

(*b*) The batch for potency, moisture, and disintegration time.

(ii) Samples required:

(*a*) The erythromycin stearate used in making the batch: 10 containers, each consisting of not less than 500 milligrams.

(*b*) The batch:

(*1*) For all tests except disintegration time: A minimum of 30 tablets.

(*2*) For disintegration time: 6 tablets.

(*c*) In case of an initial request for certification, each other ingredient used in making the batch: One package of each containing not less than 5 grams.

(4) *Fees.* $0.75 for each tablet submitted in accordance with subparagraph (3)(ii)(*b*)(*1*) of this paragraph; $3.00 for all tablets submitted in accordance with subparagraph (3)(ii)(*b*)(*2*) of this

paragraph; $4.00 for each package submitted in accordance with subparagraph (3)(ii)(*a*) and (*c*) of this paragraph.

(b) *Tests and methods of assay*—(1) *Potency*. Proceed as directed in § 148e.26 (b)(1). The erythromycin stearate content is satisfactory if it is not less than 90 percent nor more than 120 percent of the number of milligrams of erythromycin that it is represented to contain.

(2) *Moisture*. Proceed as directed in § 141a.5(a) of this chapter.

(3) *Disintegration time*. Proceed as directed in § 141a.9(c)(2) of this chapter.

§ 148e.28 Erythromycin estolate tablets with sulfonamides.

(a) *Requirements for certification*—(1) *Standards of identity, strength, quality, and purity*. Erythromycin estolate tablets with sulfonamides are tablets composed of erythromycin estolate, with suitable and harmless buffer substances, diluents, binders, lubricants, colorings, and flavorings, and suitable sulfonamides. The potency of each tablet is 125 milligrams of erythromycin. Tablets shall disintegrate within 1 hour. The moisture content is not more than 4.0 percent. The erythromycin estolate used conforms to the standards prescribed by § 148e.5(a)(1). Each other substance used, if its name is recognized in the U.S.P. or N.F., conforms to the standards prescribed therefor by such official compendium.

(2) *Labeling*. It shall be labeled in accordance with the requirements of § 148.3 of this chapter. Its expiration date is 12 months.

(3) *Request for certification; samples*. In addition to the requirements of § 148.4 of this chapter, each such request shall contain:

(i) Results of tests and assays on:

(*a*) The erythromycin estolate used in making the batch for potency, toxicity, moisture, pH, crystallinity, and identity.

(*b*) The batch for potency, disintegration time, and moisture.

(ii) Samples required:

(*a*) Erythromycin estolate used in making the batch: 10 packages, each containing not less than 300 milligrams.

(*b*) The batch:

(*1*) For all tests except disintegration time: A minimum of 30 tablets.

(*2*) For disintegration time: 6 tablets.

(*c*) In case of an initial request for certification, each other ingredient used in making the batch: One package, of each containing not less than 5 grams.

(4) *Fees*. $0.75 for each tablet submitted in accordance with subparagraph (3)(ii)(*b*)(*1*) of this paragraph; $3.00 for all tablets submitted in accordance with subparagraph (3)(ii)(*b*)(*2*) of this paragraph; $4.00 for each package submitted in accordance with subparagraphs (3)(ii) (*a*) and (*c*) of this paragraph.

(b) *Tests and methods of assay*—(1) *Potency*. Proceed as directed in § 148e.5 (b)(1), except prepare the sample in the following manner: Blend a representative number of tablets in a high-speed glass blender for 2 to 3 minutes in 100 milliliters of methyl alcohol. Add 400 milliliters of 0.1*M* potassium phosphate buffer, pH 8.0, and blend again for 2 to 3 minutes. The erythromycin estolate content is satisfactory if it is not less than 90 percent nor more than 120 percent of the number of milligrams of erythromycin that it is represented to contain.

(2) *Moisture*. Proceed as directed in § 141a.26(e) of this chapter.

(3) *Disintegration time*. Proceed as directed in § 141a.9(c) of this chapter.

§ 148e.29 Erythromycin ethylsuccinate chewable tablets.

(a) *Requirements for certification*—(1) *Standards of identity, strength, quality, and purity*. Erythromycin ethylsuccinate chewable tablets are tablets composed of erythromycin ethylsuccinate, suitable and harmless diluents, binders, buffers, colorings, and flavorings. The potency of each tablet is equivalent to either 100 milligrams of erythromycin or 200 milligrams of erythromycin. The moisture content is not more than 5 percent. The crystalline erythromycin ethylsuccinate used conforms to the standards prescribed by § 148e.7(a)(1) (i), (iii), (iv), (v), (vi), and (vii). Each other ingredient used, if its name is recognized in the U.S.P. or N.F., conforms to the standards prescribed therefor by such official compendium.

(2) *Labeling*. It shall be labeled in accordance with § 148.3 of this chapter. The expiration date is 12 months.

(3) *Request for certification; samples*. In addition to the requirements of § 148.4 of this chapter, each such request shall contain:

(i) Results of tests and assays on:

(*a*) The erythromycin ethylsuccinate used in making the batch for potency, toxicity, moisture, pH, residue on ignition, identity, and crystallinity.

(*b*) The batch for potency and moisture.

(ii) Samples required:

(*a*) The erythromycin ethylsuccinate used in making the batch: 10 packages, each consisting of 500 milligrams.

(*b*) The batch: A minimum of 30 tablets.

(*c*) In case of an initial request for certification, each other ingredient used in making the batch: One package of each, containing approximately 5 grams:

(4) *Fees*. $4.00 for each package in the samples submitted in accordance with subparagraph (3)(ii) (*a*) and (*c*) of this paragraph; $0.75 for each tablet in the sample submitted in accordance with subparagraph (3)(ii)(*b*) of this paragraph.

(b) *Tests and methods of assay*—(1) *Potency*. Proceed as directed in § 148e.1 (b)(1) of this chapter, except prepare the sample in the following manner: Blend a representative number of tablets in a high-speed glass blender with 50 milliliters of absolute methyl alcohol per tablet. Further dilute to the reference point with 0.1*M* potassium phosphate buffer, pH 8.0. Its potency is satisfactory if the tablets contain not less than 90 percent nor more than 120 percent of the number of milligrams of erythromycin that it is represented to contain.

(2) *Moisture*. Proceed as directed in § 141a.5(a) of this chapter.

§ 148e.30 Erythromycin estolate chewable tablets.

(a) *Requirements for certification*—(1) *Standards of identity, strength, quality, and purity*. Erythromycin estolate chewable tablets are tablets composed of erythromycin estolate, and suitable and harmless diluents, binders, buffers, colorings, and flavorings. The potency of each tablet is equivalent to 125 milligrams of erythromycin. The moisture content is not more than 4 percent. The erythromycin estolate used in making the batch conforms to the standards prescribed by § 148e.5(a)(1). Each other substance used, if its name is recognized in the U.S.P. or N.F., conforms to the standards prescribed therefor by such official compendium.

(2) *Labeling*. It shall be labeled in accordance with § 148.3 of this chapter. The expiration date is 12 months.

(3) *Request for certification; samples*. In addition to the requirements of § 148.4 of this chapter, each such request shall contain:

(i) Results of tests and assays on:

(*a*) The erythromycin estolate used in making the batch for potency, toxicity, moisture, pH, crystallinity, and identity.

(*b*) The batch for potency and moisture.

(ii) Samples required:

(*a*) The erythromycin estolate used in making the batch: 10 packages, each consisting of not less than 300 milligrams.

(*b*) The batch: A minimum of 30 tablets.

(*c*) In case of an initial request for certification, each other ingredient used in making the batch: One package of each, containing 5 grams.

(4) *Fees*. $4.00 for each package in the samples submitted in accordance with subparagraph (3)(ii) (*a*) and (*c*) of this paragraph; $0.75 for each tablet in the sample submitted in accordance with subparagraph (3)(ii)(*b*) of this paragraph.

(b) *Tests and methods of assay*—(1) *Potency*. Proceed as directed in § 148e.28(b)(1). The erythromycin estolate content is satisfactory if it is not less than 90 percent nor more than 115 percent of the number of milligrams of erythromycin that it is represented to contain.

(2) *Moisture*. Proceed as directed in § 141a.26(e) of this chapter.

§ 148e.31 Erythromycin ophthalmic ointment.

(a) *Requirements for certification*—(1) *Standards of identity, strength, quality, and purity*. Erythromycin ophthalmic ointment is erythromycin in a suitable and harmless ointment base. Each gram of ointment contains 5 milligrams of erythromycin. The moisture content is not more than 1 percent. The erythromycin used conforms to the standards prescribed by § 148e.1(a)(1) (i), (ii), (iii), (iv), (v), and (vii). Each other substance used, if its name is recognized in the U.S.P. or N.F., conforms to the standards prescribed therefor by such official compendium.

(2) *Labeling*. It shall be labeled in accordance with the requirements of

§ 148.3 of this chapter. Its expiration date is 12 months.

(3) *Request for certification; samples.* In addition to the requirements of § 148.4 of this chapter, each such request shall contain:

(i) Results of tests and assays on:

(*a*) The erythromycin used in making the batch for potency, toxicity, pH, moisture, residue on ignition, crystallinity, and identity.

(*b*) The batch for potency and moisture.

(ii) Samples required:

(*a*) The erythromycin used in making the batch; 10 packages, each containing 500 milligrams.

(*b*) The batch: A minimum of 5 immediate containers.

(*c*) In case of an initial request for certification, each other ingredient used in making the batch: One package of each, containing 5 grams.

(4) *Fees.* $4.00 for each immediate container or package of the sample submitted in accordance with subparagraph (3)(ii) of this paragraph.

(b) *Tests and methods of assay*—(1) *Potency.* Proceed as directed in § 148e.14 (b)(1). Its potency is satisfactory if it is not less than 90 percent nor more than 120 percent of the number of milligrams of erythromycin that it is represented to contain.

(2) *Moisture.* Proceed as directed in § 141a.8(b) of this chapter.

PART 148j—NOVOBIOCIN

Sec.

148j.1 Sodium novobiocin.
148j.2 Calcium novobiocin.
148j.3 Sodium novobiocin tablets.
148j.4 Calcium novobiocin-sulfamethizole tablets.
148j.5 Calcium novobiocin oral suspension.
148j.6 [Reserved]

AUTHORITY: The provision of this Part 148j issued under sec. 507, 59 Stat. 463, as amended 76 Stat. 785, 786, 787; 21 U.S.C.A. 357.

§ 148j.1 Sodium novobiocin.

(a) *Requirements for certification*—(1) *Standards of identity, strength, quality, and purity.* Sodium novobiocin is the crystalline monosodium salt of a kind of novobiocin or a mixture of two or more such salts. It is so purified and dried that:

(i) Its potency is not less than 800 micrograms of novobiocin per milligram, calculated on an anhydrous basis.

(ii) It is sterile.

(iii) It is nonpyrogenic.

(iv) It is nontoxic.

(v) Its moisture content is not more than 6.0 percent.

(vi) Its pH in a solution containing 25 milligrams per milliliter is not less than 6.5 and not more than 8.5.

(vii) Its residue on ignition is not less than 10.0 percent and not more than 11.5 percent.

(viii) Its specific rotation in an acid-methyl alcohol solution at 25° C. is not less than −50° and not more than −58°.

(ix) When dissolved in 0.1*M* sodium borate, it demonstrates a positive color identity test in a saturated aqueous solution of *N*,2,6-trichloroquinoneimine.

(2) *Labeling.* It shall be labeled in accordance with the requirements of § 148.3(b) of this chapter. Its expiration date is 12 months.

(3) *Request for certification; samples.* In addition to the requirements of § 148.4 of this chapter, each such request shall contain:

(i) Results of tests and assays on the batch for potency, sterility, pyrogens, toxicity, moisture, pH, residue on ignition, specific rotation, identity, and crystallinity.

(ii) Samples required:

(*a*) For all tests except sterility: 10 packages, each containing approximately 600 milligrams.

(*b*) For sterility testing: 10 packages, each containing approximately 500 milligrams.

(4) *Fees.* $5.00 for each container submitted in accordance with subparagraph (3)(ii)(*a*) of this paragraph; $10.00 for all samples submitted in accordance with subparagraph (3)(ii)(*b*) of this paragraph.

(b) *Tests and methods of assay*—(1) *Potency*—(i) *Cylinders (cups).* Use cylinders described in § 141a.1(a) of this chapter.

(ii) *Culture media.* Use ingredients that conform to the standards prescribed in the U.S.P. or N.F., if such name appears in either compendium.

(*a*) Make nutrient agar for the seed layer and for carrying the test organism as follows:

Peptone	6.0 gm.
Pancreatic digest of casein	4.0 gm.
Yeast extract	3.0 gm.
Beef extract	1.5 gm.
Dextrose	1.0 gm.
Agar	15.0 gm.
Distilled water, q.s	1,000 ml.

pH 6.5 to 6.6 after sterilization.

(*b*) Make nutrient agar for the base layer as follows:

Peptone	6.0 gm.
Yeast extract	3.0 gm.
Beef extract	1.5 gm.
Agar	15.0 gm.
Distilled water, q.s	1,000 ml.

pH 6.5 to 6.6 after sterilization.

In lieu of preparing the media from the individual ingredients specified in this subdivision, they may be made from a dehydrated mixture which, when reconstituted with distilled water, has the same composition as such media. Minor modification of the individual ingredients specified in (*a*) and (*b*) of this subdivision are permissible if the resulting media possess growth-promoting properties at least equal to the media described.

(iii) *Working standard.* Dissolve volumetrically a suitable weighed quantity (30 milligrams to 50 milligrams) of the working standard, dried as described in § 141a.5(a) of this chapter, in 2 milliliters of absolute ethyl alcohol and then add sufficient 0.1*M* potassium phosphate buffer, pH 7.8 to 8.0, to give a concentration of 1,000 micrograms of novobiocin per milliliter. This stock solution may be kept for 30 days when stored under refrigeration.

(iv) *Preparation of sample.* Dissolve the accurately weighed sample in sufficient 0.1*M* potassium phosphate buffer, pH 7.8 to 8.0, to give a stock solution of convenient concentration. Further dilute in 1.0 percent potassium phosphate buffer, pH 6.0, to give a final concentration of 0.5 microgram of novobiocin per milliliter (estimated).

(v) *Preparation of test organism.* The test organism is *Staphylococcus epidermidis* (ATCC 12228), which is maintained on slants of agar described in subdivision (ii)(*a*) of this subparagraph. Wash the organism from a recently incubated slant with 3 milliliters of sterile U.S.P. saline T.S. onto a large agar surface, such as that provided by a Roux bottle containing 300 milliliters of agar. Use sterile glass beads to aid in spreading the organism over the entire agar surface of the Roux bottle. Incubate 16 hours to 24 hours at 32° C. to 35° C. Wash the resulting growth from the agar surface with 50 milliliters of sterile U.S.P. saline T.S. Standardize the resulting bulk suspension so that a 1:25 dilution in U.S.P. saline T.S. will give 25 percent light transmission, using a suitable photoelectric colorimeter with a 580-millimicron filter and a 13-millimeter diameter test tube as an absorption cell. Run test plates to determine the quantity of the adjusted bulk suspension (usually 1.0 milliliter) to be added to each 100 milliliters of agar that will give clear, sharp zones of inhibition of appropriate size.

(vi) *Preparation of plates.* Add 21 milliliters of the agar prepared as described in subdivision (ii)(*b*) of this subparagraph to each Petri dish (20 millimeters x 100 millimeters). Distribute the agar evenly in the plates, cover with porcelain tops glazed on the outside, and allow to harden. Use plates the same day they are prepared. Melt a sufficient amount of agar described in subdivision (ii)(*a*) of this subparagraph, cool to 48° C., add the proper amount of the test organism bulk suspension as described in subdivision (v) of this subparagraph, and mix thoroughly. Add 4 milliliters of this inoculated agar to each Petri dish. Distribute the seed agar evenly in the plates, cover again, and allow to harden. After the agar has hardened, place 6 cylinders on the agar surface so that they are at approximately 60° intervals on a 2.8-centimeter radius.

(vii) *Standard curve.* Prepare the daily standard curve by further diluting the 1,000 micrograms per milliliter stock solution in 1 percent potassium phosphate buffer, pH 6.0, to obtain concentrations of 0.32, 0.40, 0.50, 0.625, and 0.78 microgram of novobiocin per milliliter. Use three plates for the determination of each point on the curve, except the 0.5 microgram per milliliter concentration, a total of 12 plates. On each of three plates, fill alternately three cylinders with the 0.5 microgram per milliliter standard, and fill the other three cylinders with the concentration under test. Thus, there will be thirty-six 0.5 microgram determinations and nine determinations for each of the other points on the curve. After the plates have incubated, read the diameters of the circles of inhibition. Average the readings of the 0.5 microgram per milliliter concentration and the readings of the point tested for each of three plates, and average also all 36 readings of the 0.5 microgram per milliliter concentrations. The average of the 36 readings of the 0.5 microgram per milliliter concentration is the correction point for the curve. Correct the average value obtained for each point to the figure it would be if the 0.5 microgram per milliliter reading for that set of three plates were the same as the correction point. Thus, if in correcting the 0.4-microgram concentration, the average of the 36 readings of the 0.5-microgram concentration is 20.0 millimeters, and the average of the 0.5-microgram concentration of this set of three plates is 19.8 milliliters, the correction is +0.2 millimeter. If the average reading of the 0.4-microgram concentration of these same three plates is 19.0 millimeters, the corrected value is 19.2 millimeters. Plot these corrected values, including the average of the 0.5 microgram per milliliter concentration, on two-cycle semilog paper, placing the concentration in micrograms per milliliter on the logarthmic scale and the diameter of the zone of inhibition on the arithmetic scale. Draw the standard curve through these points either by inspection or by means of the following equations:

$$L=\frac{3a+2b+c-e}{5},$$

$$H=\frac{3e+2d+c-a}{5},$$

where:

L=Calculated zone diameter for the lowest concentration of the standard curve;

H=Calculated zone diameter for the highest concentration of the standard curve;

c=Average zone diameter of 36 readings of the 0.5 microgram per milliliter standard;

a, b, d, e=Corrected average values for the 0.32, 0.40, 0.625, and 0.78 microgram per milliliter standard solutions, respectively.

Plot the values obtained for L and H and connect with a straight line.

(viii) *Assay.* Use three plates for each sample. Fill three cylinders on each plate with the standard 0.5 microgram per milliliter solution and three cylinders with the 0.5 microgram per milliliter (estimated) sample, alternating standard and sample. Incubate all plates, including those containing the standard curve, at 32° C.–35° C. overnight, and measure the diameter of each circle of inhibition. To estimate the potency of the sample, average the zone readings of the standard and the zone readings of the sample on the three plates used. If the sample gives a larger zone size than the average of the standard, add the difference between them to the 0.5 microgram per milliliter zone on the standard curve. If the average sample value is lower than the standard value, subtract the difference between them from the 0.5 microgram per milliliter value on the standard curve. From the curve, read the potencies corresponding to these corrected values of zone sizes.

(2) *Sterility.* Use 500 milligrams, or the entire contents if less than 500 milligrams, from each immediate container tested, and proceed as directed in § 141a.2 of this chapter, except that neither penicillinase nor the control tube is used in the test for bacteria, and use 50 milligrams in lieu of 500 milligrams in the test for yeasts and molds. Adjust the pH of the Sabouraud medium to 7.4 with NaOH.

(3) *Pyrogens.* Proceed as directed in § 141a.3 of this chapter, using as a test dose 1.0 milliliter per kilogram of a solution prepared by diluting the sample to 10 milligrams of novobiocin per milliliter with sterile, pyrogen-free U.S.P. saline T.S.

(4) *Toxicity.* Proceed as directed in § 141a.4 of this chapter, except use sterile U.S.P. saline T.S. as a diluent, and administer a test dose of 0.5 milliliter of a solution containing 4 milligrams of novobiocin per milliliter.

(5) *Moisture.* Proceed as directed in § 141a.5(a) of this chapter.

(6) *pH.* Proceed as directed in § 141a.5(b) of this chapter, using a solution containing 25 milligrams of sodium novobiocin per milliliter.

(7) *Residue on ignition.* Proceed as directed in § 141e.401(g) of this chapter.

(8) *Specific rotation.* Accurately weigh approximately 1.25 grams of the sample in a 25-milliliter glass-stoppered volumetric flask. Prepare an acid-methyl alcohol solution by diluting 1.0 milliliter of concentrated hydrochloric acid to a volume of 100 milliliters with absolute methyl alcohol and mix well. Dissolve the sample in about 15-milliliters of the acid-methyl alcohol solution. Adjust to volume with the acid-methyl alcohol solution and mix well. Transfer the solution to a 200-millimeter tube, and determine the angular rotation in a suitable polarimeter, using sodium light or a 5893 Angstrom filter. Calculate the specific rotation on the anhydrous basis.

(9) *Identity.* (i) Using 0.1*M* aqueous sodium borate as a diluent, prepare 10 milliliters of a solution containing the equivalent of 1 milligram (approximate) of novobiocin per milliliter.

(ii) Prepare a saturated aqueous solution of *N*,2,6-trichloroquinoneimine by shaking continuously for 30 minutes in a dark bottle 25 milligrams of *N*,2,6-trichloroquinoneimine in 100 milliliters of distilled water. Let stand 2 hours after shaking. Store in the dark bottle.

(iii) Add 1.0 milliliter of the saturated *N*,2,6-trichloroquinoneimine solution to 4 milliliters of the novobiocin solution. Mix well and heat in a water bath at 37° C. for 10 minutes. The development of a blue color is a positive test for the presence of novobiocin. To 2 milliliters of the blue solution, add 2 milliliters of *N*-butyl alcohol and shake well. A green color should develop in the butyl alcohol layer. To the other 2-milliliter portion of the blue solution, add 2 milliliters of benzene (c.p.), and shake well. A pink color should be developed in the benzene layer.

(10) *Crystallinity.* Proceed as directed in § 141a.5(c) of this chapter.

§ 148j.2 Calcium novobiocin.

(a) *Requirements for certification*—(1) *Standards of identity, strength, quality, and purity.* Calcium novobiocin is the crystalline calcium salt of a kind of novobiocin or a mixture of two or more such salts. It is so purified and dried that:

(i) Its potency is not less than 800 micrograms per milligram, expressed in terms of novobiocin on an anhydrous basis.

(ii) It is nontoxic.

(iii) Its moisture content is not more than 10 percent.

(iv) Its pH in a saturated aqueous suspension containing 25 milligrams per milliliter is not less than 6.5 and not more than 8.5.

(v) Its specific rotation in an acid-methyl alcohol solution at 25° C. is not less than −50° and not more than −58°.

(vi) It demonstrates a positive color identity test.

(2) *Labeling.* It shall be labeled in accordance with the requirements of § 148.3(b) of this chapter. Its expiration date is 12 months.

(3) *Request for certification; samples.* In addition to the requirements of § 148.4 of this chapter, each such request shall contain:

(i) Results of tests and assays on the batch for potency, toxicity, moisture, pH, specific rotation, identity, and crystallinity.

(ii) Samples required: 10 packages, each containing approximately 500 milligrams.

(4) *Fees.* $4.00 for each container in the sample submitted in accordance with subparagraph (3)(ii) of this paragraph.

(b) *Tests and methods of assay*—(1) *Potency.* Proceed as directed in § 148j.1(b)(1), except prepare the stock solution of the sample by dissolving in 5 milliliters of absolute ethyl alcohol and then diluting with sufficient 0.1*M* potassium phosphate buffer, pH 8.0, to give a final concentration of 1,000 micrograms (estimated) per milliliter. Dilute an aliquot of the stock solution with 1 percent potassium phosphate buffer, pH 6.0, to an estimated concentration of 0.5 microgram per milliliter.

(2) *Toxicity.* Proceed as directed in § 141a.4 of this chapter, except use sterilized U.S.P. saline T.S. as the diluent, and inject 0.5 milliliter of a solution containing the equivalent of 2 milligrams of novobiocin per milliliter.

(3) *Moisture.* Proceed as directed in § 141a.5(a) of this chapter.

(4) *pH.* Proceed as directed in § 141a.5(b) of this chapter, using a saturated aqueous solution prepared by suspending 25 milligrams of calcium novobiocin per milliliter.

(5) *Specific rotation.* Proceed as directed in § 148j.1(b)(8).

(6) *Identity.* Proceed as directed in § 148j.1(b)(9).

(7) *Crystallinity.* Proceed as directed in § 141a.5(c) of this chapter.

§ 148j.3 Sodium novobiocin tablets.

(a) *Requirements for certification*—(1) *Standards of identity, strength, quality, and purity.* Sodium novobiocin tablets are tablets that contain sodium novobiocin, with or without one or more suitable and harmless buffer substances, diluents, binders, and lubricants. Each tablet contains 125 milligrams or 250 milligrams of novobiocin. The 125-milligram tablet contains 375 milligrams of sulfamethizole. Its moisture content is not more than 3 percent. The tablets distintegrate within 1 hour. The sodium novobiocin used conforms to the standards prescribed by § 148j.1(a)(1)(i), (iv), (v), (vi), (vii), (viii), and (ix). Each other substance used, if its name is recognized in the U.S.P. or N.F., shall conform to the standards prescribed therefor by such official compendium.

(2) *Labeling.* It shall be labeled in accordance with § 148.3 of this chapter. Its expiration date is 12 months.

(3) *Request for certification; samples.* In addition to the requirements of § 148.4 of this chapter, each such request shall contain:

(i) Results of tests and assays on:

(*a*) Sodium novobiocin used in making the batch for potency, toxicity, moisture, pH, residue on ignition, specific rotation, identity, and crystallinity.

(*b*) The batch for potency, moisture, disintegration time.

(ii) Samples required:

(*a*) Sodium novobiocin used in making the batch: 10 packages, each containing approximately 500 milligrams.

(*b*) The batch:

(*1*) For all tests except disintegration time: Minimum of 30 tablets.

(*2*) For disintegration-time: Six tablets.

(*c*) In case of an initial request for certification, each other ingredient used in making the batch: One package of each, containing approximately 5 grams.

(4) *Fees.* $0.75 for each tablet in the sample submitted in accordance with subparagraph (3)(ii)(*b*)(*1*) of this paragraph; $3.00 for all tablets in the sample submitted in accordance with subparagraph (3)(ii)(*b*)(*2*) of this paragraph; $4.00 for each immediate container submitted in accordance with subparagraph (3)(ii) (*a*) and (*c*) of this paragraph.

(b) *Tests and methods of assay*—(1) *Potency.* Proceed as directed in § 148j.1(b)(1), except prepare the sample by placing a representative number of tablets in a high-speed glass blender with sufficient 0.1*M* potassium phosphate buffer, pH 7.8 to 8.0, to give a stock solution of convenient concentration. The content of novobiocin is satisfactory if it is not less than 90 percent and not more than 120 percent of the number of milligrams that it is represented to contain.

(2) *Moisture.* Proceed as directed in § 141a.5(a) of this chapter.

(3) *Disintegration time.* Proceed as directed in § 141a.9(c) of this chapter.

§ 148j.4 Calcium novobiocin-sulfamethizole tablets.

(a) *Requirements for certification*—(1) *Standards of identity, strength, quality, and purity.* Calcium novobiocin-sulfamethizole tablets are tablets composed of calcium novobiocin and sulfamethizole, with one or more suitable and harmless colorings, binders, diluents, and lubricants. Each tablet contains 125 milligrams of novobiocin and 250 milligrams of sulfamethizole. Its moisture content is not more than 10.0 percent. The tablets disintegrate within 1 hour. The calcium novobiocin used meets the standards prescribed by § 148j.2(a)(1) of this chapter. Each other substance used, if its name appears in the U.S.P. or N.F., conforms to the standards prescribed therefor by such official compendium.

(2) *Labeling.* It shall be labeled in accordance with the requirements of § 148.3 of this chapter. Its expiration date is 12 months.

(3) *Request for certification; samples.* In addition to the requirements of § 148.4 of this chapter, each such request shall contain:

(i) Results of tests and assays on:

(*a*) The calcium novobiocin used in making the batch for potency, toxicity, moisture, pH, specific rotation, identity, and crystallinity.

(*b*) The batch for potency, moisture, and disintegration time.

(ii) Samples required:

(*a*) The calcium novobiocin used in making the batch: 10 packages, each containing approximately 500 milligrams.

(*b*) The batch:

(*1*) For all tests except disintegration time: Minimum of 30 tablets.

(*2*) For disintegration time: Six tablets.

(*c*) In case of an initial request for certification, each other ingredient used in making the batch: One package of each, containing not less than approximately 5 grams.

(4) *Fees.* $4.00 for each container in the samples submitted in accordance with subparagraph (3)(ii)(*a*) and (*c*) of this paragraph; $0.75 for each tablet submitted in accordance with subparagraph (3)(ii)(*b*)(*1*) of this paragraph; $3.00 for all tablets submitted in accordance with subparagraph (3)(ii)(*b*)(*2*) of this paragraph.

(b) *Tests and methods of assay*—(1) *Potency.* Blend a representative number of tablets in a high-speed glass blender for 3 to 5 minutes with sufficient absolute ethyl alcohol to give a stock solution of convenient concentration. Proceed further as directed in § 148j.2(b)(1). The content of novobiocin is satisfactory if it is not less than 90 percent and not more than 120 percent of the number of milligrams that it is represented to contain.

(2) *Moisture.* Proceed as directed in § 141a.5(a) of this chapter.

(3) *Disintegration time.* Proceed as directed in § 141a.9(c) of this chapter.

§ 148j.5 Calcium novobiocin oral suspension.

(a) *Requirements for certification*—(1) *Standards of identity, strength, quality, and purity.* Calcium novobiocin oral suspension is a suspension containing calcium novobiocin and one or more suitable and harmless diluents, preservatives, suspending agents, surfactants, flavorings, and colorings in purified water. Each milliliter contains 25 milligrams of novobiocin. The pH is not less than 6.0 and not more than 7.5. The calcium novobiocin used conforms to the standards prescribed by § 148j.2(a)(1)(i), (ii), (iv), and (vi). If sodium novobiocin is reacted with a suitable calcium salt to form calcium novobiocin, the sodium novobiocin used conforms to the standards prescribed by § 148j.1(a)(1)(i), (iv), (vi), (vii), (viii), and (ix). Each other substance used, if its name is recognized in the U.S.P. or N.F., conforms to the standards prescribed therefor by such official compendium.

(2) *Labeling.* It shall be labeled in accordance with § 148.3 of this chapter. Its expiration date is 12 months.

(3) *Request for certification; samples.* In addition to the requirements of § 148.4 of this chapter, each such request shall contain:

(i) Results of tests and assays on:

(*a*) The calcium novobiocin used in making the batch for potency, toxicity, pH, crystallinity, identity, and specific rotation. If sodium novobiocin is used in making the batch: Potency, toxicity, pH, residue on ignition, specific rotation, identity, and crystallinity.

(*b*) The batch for potency and pH.

(ii) Samples required:

(*a*) The calcium novobiocin or the sodium novobiocin used in making the batch: 10 packages, each containing approximately 500 milligrams.

(*b*) The batch: Minimum of 5 immediate containers.

(*c*) In case of an initial request for certification, each other ingredient used in making the batch: One package of each, containing not less than 5 grams.

(4) *Fees.* $4.00 for each package in the samples submitted in accordance with subparagraph (3)(ii) of this paragraph.

(b) *Tests and methods of assay*—(1) *Potency.* Remove a representative sample of the syrup with a suitable syringe, place into a high-speed glass blender with sufficient absolute ethyl alcohol to give a concentration (estimated) of 1,000 micrograms per milliliter. Blend for 3 to 5 minutes. Proceed further as directed in § 148j.2(b)(1). Its novobiocin content is satisfactory if it contains not less than 90 percent and not more than 120 percent of the number of milligrams that it is represented to contain.

(2) *pH.* Proceed as directed in § 141a.5(b) of this chapter, using the undiluted syrup.

PART 148o—PAROMOMYCIN

Sec.

148o.1 Paromomycin sulfate.
148o.2 Paromomycin sulfate capsules.
148o.3 Paromomycin sulfate syrup.

AUTHORITY: The provisions of this part 148o.3 issued under sec. 507, 59 Stat. 463, as amended 76 Stat. 785, 786, 787; 21 U.S.C.A. 357.

§ 148o.1 Paromomycin sulfate.

(a) *Requirements for certification*—(1) *Standards of identity, strength, quality, and purity.* Paromomycin sulfate is the sulfate salt of a kind of paromomycin or a mixture of two or more such salts. It is a creamy-white to light-yellow powder. It is so purified and dried that:

(i) Its potency is not less than 675 micrograms per milligram on an anhydrous basis.

(ii) It is nontoxic.

(iii) Its moisture content is not more than 5.0 percent.

(iv) The pH of a 3.0 percent acqueous solution is not less than 5.0 and not more than 7.5.

(v) Its specific rotation at 25° C. in water is not less than $+50°$ and not more than $+55°$ on an anhydrous basis.

(vi) Its residue on ignition is not more than 2.0 percent.

(2) *Labeling.* It shall be labeled in accordance with the requirements of § 148.3(b) of this chapter. Its expiration date is 12 months.

(3) *Request for certification; samples.* In addition to the requirements of § 148.4 of this chapter, each such request shall contain:

(i) Results of tests and assays on the batch for potency, toxicity, moisture, pH, specific rotation, and residue on ignition.

(ii) Samples of the batch: 10 packages, each containing approximately 500 milligrams.

(4) *Fees.* $4.00 for each container in the sample submitted in accordance with subparagraph (3)(ii) of this paragraph.

(b) *Tests and methods of assay*—(1) *Potency.* Use either of the following methods:

(i) *Plate assay using Staphylococcus epidermidis*—(*a*) *Cylinders (cups).* Use cylinders described in § 141a.1(a) of this chapter.

(*b*) *Culture media.* Use ingredients that conform to the standards prescribed by the U.S.P. or N.F.

(*1*) Make nutrient agar for maintaining the test organism as follows:

Peptone	6.0 gm.
Pancreatic digest of casein	4.0 gm.
Yeast extract	3.0 gm.
Beef extract	1.5 gm.
Dextrose	1.0 gm.
Agar	15.0 gm.
Distilled water, q.s	1,000.0 ml.

pH 6.5 to 6.6 after sterilization.

In lieu of preparing the medium from the individual ingredients specified in (*b*)(*1*) of this subdivision, it may be made from a dehydrated mixture which, when reconstituted with distilled water, has the same composition of such medium. Minor modifications of the individual ingredients specified in (*b*)(*1*) of this subdivision are permissible if the resulting medium possesses growth-promoting properties at least equal to the medium described.

(*2*) Use the nutrient agar described in this subsection for the seed layer and base layer, except that its pH after sterilization is 7.8 to 8.0.

(*c*) Working standard. Dry approximately 30 milligrams of the working standard for 3 hours at 60° C. and a pressure of 5 millimeters or less. Determine the weight of the dried standard and dissolve in sufficient 0.1*M* potassium phosphate buffer, pH 8.0, to give a concentration of 1,000 micrograms of paromomycin per milliliter. This stock solution may be kept in the refrigerator for 3 weeks.

(*d*) *Preparation of sample.* Dissolve the sample in sufficient 0.1*M* potassium phosphate buffer, pH 8.0, to give a convenient stock solution. Further dilute in 0.1*M* potassium phosphate buffer, pH 8.0, to give a final concentration of 1.0 microgram per milliliter (estimated).

(*e*) *Preparation of test organism.* The test organism is *Staphylococcus epidermidis* (ATCC 12228), which is maintained on slants or agar described in (*b*)(*1*) of this subdivision. Wash the organism from the agar slant with 3 milliliters of sterilized U.S.P. saline T.S. onto a large agar surface such as that provided by a Roux bottle containing 300 milliliters of the agar described in (*b*)(*1*) of this subdivision. Spread the suspension of organisms over the entire agar surface with the aid of sterile glass beads. Incubate for 24 hours at 32° C.–35° C., and then wash the resulting growth from the agar surface with 50 milliliters of sterilized U.S.P. saline T.S. Standardize the suspension, so that a 1:25 dilution will give 25 percent light transmission, using a suitable photoelectric colorimeter with a 580-millimicron filter and a 13-millimeter diameter test tube as an absorption cell. Run plates to determine the quantity of the adjusted bulk suspension (usually 0.16 milliliter) that should be added to each 100 milliliters of agar to give clear, sharp zones of inhibition of appropriate size.

(*f*) *Preparation of plates.* Add 21 milliliters of the agar prepared as described in (*b*)(*2*) of this subdivision to each Petri dish (20 millimeters x 100 millimeters). Distribute the agar evenly in the plates and allow it to harden. Use plates the same day they are prepared. Melt a sufficient amount of agar described in (*b*)(*2*) of this subdivision, cool to 48° C., add the proper amount of the test organism as described in (*e*) of this subdivision, and mix thoroughly. Add 4 milliliters of this inoculated agar to each Petri dish. Distribute the agar evenly in the plates, cover, and allow to harden. After the agar has hardened, place 6 cylinders on the agar surface so that they are at approximately 60° intervals on a 2.8-centimeter radius.

(*g*) *Standard curve.* Prepare the daily standard curve by further diluting the 1,000 micrograms per milliliter stock solution in 0.1*M* potassium phosphate buffer, pH 8.0, to obtain concentrations of 0.64, 0.80, 1.00, 1.25, and 1.56 micrograms per milliliter. The 1.0-microgram per milliliter solution is the reference concentration. Use three plates for the determination of each point on the curve, except the 1.0-microgram per milliliter concentration, a total of 12 plates. On each of three plates fill three cylinders with the 1.0 microgram per milliliter standard and the other three cylinders with the concentration under test. Thus, there will be thirty-six 1-microgram determinations and 9 determinations for each of the other points on the curve. After the plates have incubated overnight at 32° C.–35° C., read the diameters of the circles of inhibition in the plates. Average the readings of the 1.0 microgram per milliliter concentration and the readings of the point tested for each set of three plates, and average also all 36 readings of the 1.0 microgram per milliliter concentration. The average of the 36 readings of the 1.0 microgram per milliliter concentration is the correction point of the curve. Correct the average value obtained for each point to the figure it would be if the 1.0 microgram per milliliter reading for that set of three plates were the same as the correction point. Thus, if in correcting the 0.80-microgram concentration, the average of 36 readings of the 1.0-microgram concentration were 20.0 millimeters, and the average of the 1.0-microgram concentration of this set of three plates were 19.8 millimeters, the correction would be +0.2 millimeter. If the average reading of the 0.80-microgram concentration of the same three plates were 19.0 millimeters, the corrected value would be 19.2 millimeters. Plot these corrected values, including the average of the 1.0 microgram per milliliter concentration, on 2-cycle semilog paper, using the concentration in micrograms per milliliter as the ordinate (the logarithmic scale) and the diameter of the zone of inhibition as the abscissa. Draw the standard curve through these points, either by inspection or by means of the following equations:

$$L=\frac{3a+2b+c-e}{5},$$

$$H=\frac{3e+2d+c-a}{5},$$

where:

L=Calculated zone diameter for the lowest concentration of the standard curve;

H=Calculated zone diameter for the highest concentration of the standard curve;

c=Average zone diameter of 36 readings of the 1.0 microgram per milliliter standard;

a, b, d, e=Corrected average values for the 0.64, 0.80, 1.25, and 1.56 micrograms per milliliter standard solutions, respectively.

Plot the values obtained for L and H and connect with a straight line.

(*h*) *Assay.* Use three plates for each sample. Fill three cylinders on each plate with the standard 1.0 microgram per milliliter solution and three cylinders with the 1.0 microgram per milliliter (estimated) sample, alternating standard and sample. Incubate all plates, including those containing the standard curve, at 32° C.—35° C. overnight, and measure the diameter of each circle of inhibition. To estimate the potency of the sample, average the zone readings of the standard and the zone readings of the sample on the three plates used. If the sample gives a larger zone size than the average of the standard, add the difference between them to the 1.0 microgram per milliliter zone on the standard curve. If the average sample value is lower than the standard value, subtract the difference between them from the 1.0 microgram per milliliter value on the curve. From the standard curve, read the potencies corresponding to these corrected values of zone sizes.

(ii) *Plate assay using Bacillus subtilis.* As an alternative method, proceed as directed in § 141b.101 (a) through (i) of this chapter, except that:

(*a*) In lieu of the directions in § 141b.101(b) of this chapter, prepare the nutrient agar for the base and seed layers as follows:

Beef extract	6.0 gm.
Peptone	10.0 gm.
Agar	15.0 gm.
Distilled water, q.s	1,000.0 ml.

pH 7.8–8.0 after sterilization.

In lieu of preparing the medium from the individual ingredients specified in (*a*) of this subdivision, it may be made from a dehydrated mixture which, when reconstituted with distilled water, has the same composition of such medium. Minor modifications of the individual ingredients specified are permissible if the resulting medium possesses growth-promoting properties at least equal to the medium described.

(*b*) Prepare the working standard stock solution as directed in subdivision (i)(*c*) of this subparagraph, and in lieu of the concentrations for the standard curve as prescribed in § 141b.101(d) of this chapter, prepare concentrations of 1.28, 1.60, 2.00, 2.50, and 3.12 micrograms per milliliter from the stock solution and use 2.00 micrograms per milliliter concentration as the reference point.

(*c*) In lieu of the directions in § 141b.101(e) of this chapter, dilute the sample to a final concentration of 2.0 micrograms (estimated) per milliliter.

(2) *Toxicity.* Proceed as directed in § 141d.305(b) of this chapter, except administer 0.5 milliliter of a solution of the drug in sterilized distilled water containing 8.0 milligrams per milliliter.

(3) *Moisture.* Proceed as directed in § 141a.5(a) of this chapter.

(4) *pH.* Proceed as directed in § 141a.5(b) of this chapter, using a 3.0 percent aqueous solution.

(5) *Specific rotation.* Accurately weigh approximately 1.25 grams of the sample into a 25-milliliter volumetric flask. Dissolve in a few milliliters of water, add water to volume, and mix. Transfer the solution to a 200-millimeter tube and determine the angular rotation in a suitable polarimeter, using a sodium light or a 5,893 Angstrom filter. Calculate the specific rotation on an anhydrous basis.

(6) *Residue on ignition.* Place approximately 1 gram of the sample, accurately weighed, in a tared, metal-free procelain crucible, and add 2 milliliters of concentrated H_2SO_4. Completely char on low flame, raising the temperature gradually until fumes of SO_3 disappear. Ignite at a dull-red heat or in a muffle furnace at 1,100° F., cool, and weigh.

§ 148o.2 Paromomycin sulfate capsules.

(a) *Requirements for certification*—(1) *Standards of identity, strength, quality, and purity.* Paromomycin sulfate capsules is paromomycin sulfate enclosed in a suitable and harmless gelatin capsule. Each capsule contains 250 milligrams of paromomycin. The moisture content is not more than 7.0 percent. The paromomycin sulfate used conforms to the standards prescribed therefor by § 148o.1(a)(1).

(2) *Labeling.* It shall be labeled in accordance with the requirements of § 148.3 of this chapter. Its expiration date is 12 months.

(3) *Request for certification; samples.* In addition to the requirements of § 148.4 of this chapter, each such request shall contain:

(i) Results of tests and assays on:

(*a*) The paromomycin sulfate used in making the batch for potency, toxicity, moisture, pH, specific rotation, and residue on ignition.

(b) The batch for potency and moisture.

(ii) Samples required:

(*a*) The paromomycin used in making the batch: 10 packages, each containing approximately 500 milligrams.

(*b*) The batch: A minimum of 30 capsules.

(*c*) In case of an initial request for certification, each other ingredient used: One package of each, containing not less than 5 grams.

(4) *Fees.* $0.75 for each capsule in the sample submitted in accordance with subparagraph (3)(ii)(*b*) of this paragraph; $4.00 for each package in the samples submitted in accordance with subparagraph (3)(ii)(*a*) and (*c*) of this paragraph.

(b) *Tests and methods of assay*—(1) *Potency.* Proceed as directed in § 148o.1 (b)(1), except prepare a stock solution of convenient concentration by pooling the entire contents of a representative number of capsules in an appropriate-sized volumetric flask and dissolve with 0.1*M* potassium phosphate buffer, pH 8.0. The paromomycin content is satisfactory if it contains not less than 90 percent and not more than 125 percent of the number of milligrams that each capsule is represented to contain.

(2) *Moisture.* Proceed as directed in § 141a.5(a) of this chapter.

§ 148o.3 Paromomycin sulfate syrup.

(a) *Requirements for certification*—(1) *Standards of identity, strength, quality, and purity.* Paromomycin sulfate syrup is a syrup that contains paromomycin sulfate and one or more suitable and harmless solvents, flavorings, colorings, preservatives, and buffers in water. It contains a quantity of sucrose sufficient to make a syrup. Each milliliter contains 25 milligrams of paromomycin per milliliter. Its pH is not less than 7.5 and not more than 8.5. The paromomycin sulfate used conforms to the requirements of § 148o.1(a)(1) (i), (ii), (iv), (v), and (vi). Each other substance used, if its name is recognized in the U.S.P. or N.F., conforms to the standards prescribed therefor by such official compendium.

(2) *Labeling.* It shall be labeled in accordance with the requirements of § 148.3 of this chapter. Its expiration date is 12 months.

(3) *Request for certification; samples.* In addition to the requirements of § 148.4 of this chapter, each such request shall contain:

(i) Results of tests and assays for:

(*a*) The paromomycin sulfate used in making the batch for potency, toxicity, pH, specific rotation, and residue on ignition.

(*b*) The batch for potency and pH.

(ii) Samples required:

(*a*) The paromomycin sulfate used in making the batch: 10 packages, each containing approximately 500 milligrams.

(*b*) The batch: Minimum of 5 immediate containers.

(*c*) In case of an initial request for certification, each other ingredient used in making the batch: One package of each, containing not less than 5 grams.

(4) *Fees.* $4.00 for each package in the samples submitted in accordance with subparagraph (3)(iii) of this paragraph.

(b) *Tests and methods of assay*—(1) *Potency.* Proceed as directed in § 148o.1 (b)(1), except prepare the sample for assay by removing an appropriate aliquot of the syrup with a suitable syringe and transfer to an appropriate volumetric flask. Dilute to volume with distilled water and mix well. Make proper estimated dilutions of an aliquot to the prescribed reference point with 0.1*M* potassium phosphate buffer, pH 8.0. The potency is satisfactory if it contains not less than 90 percent and not more than 130 percent of the number of milligrams of paromomycin that it is represented to contain.

(2) *pH.* Proceed as directed in § 141a.5(b) of this chapter, using the undiluted sample.

It is not deemed necessary to provide notice of proposed rulemaking in the case of the two new antibiotic drugs not included in the notice published in the FEDERAL REGISTER May 2, 1963, since these are formulations of the basic antibiotic drug included in the proposal.

Effective date. This order shall become effective 60 days from the date of its publication in the FEDERAL REGISTER.

(Sec. 507, 59 Stat. 463 as amended; 21 U.S.C. 357)

Dated: June 4, 1964.

GEO. P. LARRICK,
Commissioner of Food and Drugs.

[F.R. Doc. 64-5746; Filed, June 12, 1964; 8:49 a.m.]